

Massachusetts Tuberculosis Nursing Case Management Protocols

Tuberculosis
Elimination
Achieved through
Management

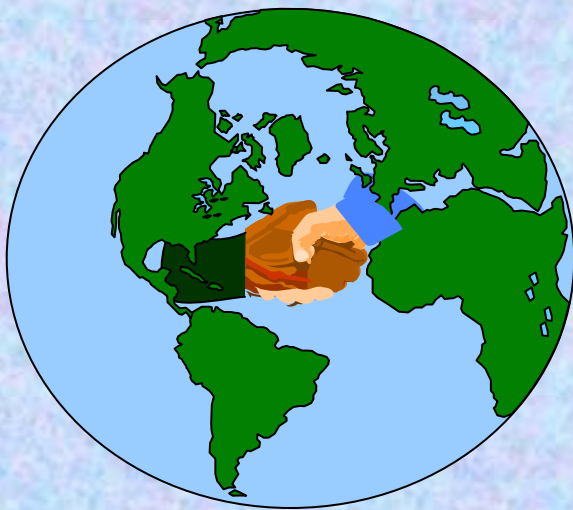


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VII. Commonwealth of Massachusetts Regulations

1. 105 CMR 350.000 Determining Active Tuberculosis
2. 105 CMR 360.000 Tuberculosis Treatment Unit Standards for Admission, Treatment, and Discharge
3. 105 CMR 365.000 Standards for Management of Tuberculosis Outside Hospitals
4. Procedure for Compulsory Hospitalization
5. Local Certification Form

VIII. Forms Section

MDPH-TB03	Epidemiologic Report on a Tuberculosis Case (contact form)
	Letter to Private Providers for Contact Follow-up
MDPH-TB04A	Initial Clinical Evaluation Form & Instructions
MDPH-TB04B	TB History Form & Instructions
MDPH-TB05	Case/Suspect Follow Up Form
MDPH-TB06	Preventive Therapy Follow Up Form
MDPH-TB07	TB Case/Suspect Reporting Form
MDPH-TB09	Drug O'Gram
MDPH-TB11	Directly Observed Therapy Log
MDPH-TB12	Patient Contract for Self-Administered Therapy
MDPH-TB13	Patient Contract for Directly Observed Therapy
MDPH-TB14	HIV Risk Assessment Tool
MDPH TB15	Drugs to Treat TB: Doses and Special Considerations chart
MDPH TB16	Source Case Investigation Policy and Procedure

I. INTRODUCTION

Theoretical Framework: "The fundamental focus of case management is to integrate, coordinate, and advocate for individuals, families, and groups requiring extensive services, ensuring that patients receive appropriate, individualized and cost-effective care within a system of services."¹ It is a system of patient care that focuses on the achievement of outcomes within specified time frames and with the appropriate use of resources. The emphasis of care changes from a task orientation to the outcomes of medical and nursing interventions throughout an episode of illness and/or treatment.

Case management is an effective method for use in tuberculosis control to ensure patients complete treatment. This model utilizes a team concept and is based on a philosophical and practical approach built on trusting relationships with the patient as a partner, which provides individualized care, patient education, advocacy, and promotes adherence and treatment completion.

Goal: To have patients complete an appropriate and effective course of anti-tuberculosis treatment in the shortest time possible, without interruption in therapy, using the least restrictive measures indicated.

Treatment Standard of Care: Evaluate every suspected and confirmed case of tuberculosis for the need for directly observed therapy (DOT) based on an assessment of risk factors for non-adherence. For persons on therapy for TB disease without any known risk factors for nonadherence, the Division recommends self-administered therapy, using fixed-dose combination pills (rifater for the initial phase and rifamate for the continuation phase) as the standard of care.

Legal Authority: The Commonwealth of Massachusetts Regulations, Standards for Management of Tuberculosis Outside Hospitals, 105 CMR 365.000 provides the legal authority for tuberculosis control in Massachusetts. These protocols and standards were developed based on this regulatory framework.

A. Nursing Case Management Model:

1. Indirect Case Management

In Massachusetts (outside Boston), every suspect and confirmed case of TB is currently referred to the Tuberculosis Surveillance Area (TSA) nurse. The regionally-

¹Bower, K. Nursing Case Management, Kansas City, MO, 1992, American Nurses Association Publishing Co.

based TSA nurses are notified of potential cases through several mechanisms: 1) formal reports from the health care providers or local health departments to the Division, 2) receipt of a positive bacteriology smear or culture report from the State Mycobacteriology Laboratory, 3) receipt of a TB clinic form for a patient seen at one of the 27 state-funded TB clinics, or 4) a telephone call from a local health department/Board of Health (BOH) nurse or other health care provider.

The TSA nurses provide consultative support to the local BOH nurses who have the responsibility for direct patient management. This follow-up on the local level varies from community to community based on local resources and the incidence of tuberculosis reported in the community. In some communities, the BOH may contract with a home health care agency (e.g. a Visiting Nurse Association) to provide the required nursing case management services. The Division recommendations for case management by the local BOH nurse are based on those from the Centers for Disease Control and Prevention (CDC) and include, at a minimum, an initial case investigation and monthly visits. Because the complexity of care of patients is increasing due to multiple factors, at the same time resources are diminishing, it is becoming more difficult to get persons through an effective course of therapy.

The TSA nurse's primary goal is to follow the case until discharged from the Case Registry for one of the following reasons: 1) the suspected case is determined not to have tuberculosis, 2) the person completes an appropriate and effective course of treatment, 3) the person moves to Boston or out of state, dies, or is completely lost to follow-up. Persons who move to Boston are referred to the Boston Public Health Commission TB Program for follow-up; persons moving out of state are referred to the relevant country or state health department TB control program.

The TSA nurses work collaboratively with local nurses to determine the level of involvement and intensity of follow-up measures needed with patients to ensure adherence to therapy. Possible interventions include the assignment of an outreach educator (ORE) for weekly to monthly home visits, twice or thrice DOT, voluntary hospitalization, and compulsory (involuntary) hospitalization. The TSA nurses also advise local nurses on the appropriate contacts to screen and the evaluation and referral of patients.

2. Direct Case Management

All persons with confirmed and clinically suspected tuberculosis shall have a nurse designated by the local BOH as the direct case manager who will work in consultation with the regional TSA nurse, as necessary, to manage persons with confirmed or clinically suspected tuberculosis. This case management is required regardless of the source of health care (public or private) and the ability to pay for

services or medications.² Utilization of a nursing case management model at the local level in the follow-up of tuberculosis patients provides a framework within which to deliver quality-nursing care and effect positive outcomes.

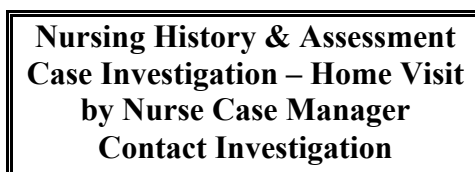
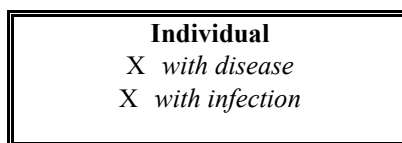
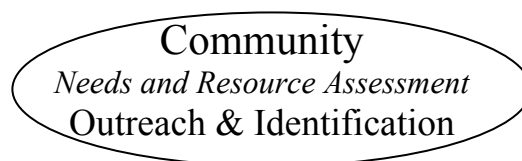
Consultation available to local nurses by the TSA nurses assists the local nurse to implement a care plan, which is individualized and specific and will enable the patient to complete an effective course of treatment in the shortest time possible, while taking into consideration the resources available in the community. The Division employs several community ORE targeted to specific higher-risk communities or populations who work under the supervision of the TSA nurses and the Assistant Director of Patient Management Services. This process should result in continuous quality improvement through more frequent monitoring to ensure that the patient is following the care plan.

B. The Case Management Process:

A comprehensive nursing assessment is performed by the BOH-designated direct case manager from the perspective of the patient's personal and psychosocial needs, to identify factors which may affect adherence, access to appropriate health care, and barriers to care. Assessment of the patient's clinical status, including the degree of infectiousness, risk factors for drug resistance, nonadherence, and/or HIV infection helps the nurse develop an individualized nursing care plan, and implement therapeutic interventions, using the least restrictive measures appropriate for the patient. Not any one intervention will be appropriate for all patients, and measures that are more restrictive may be necessary for some patients. These interventions may need to be changed and priorities re-assessed over time, as the patient's health status or lifestyle changes.

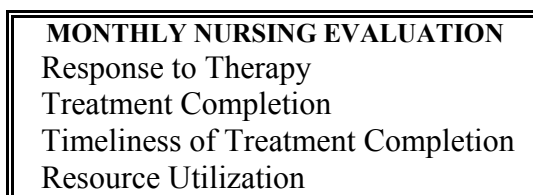
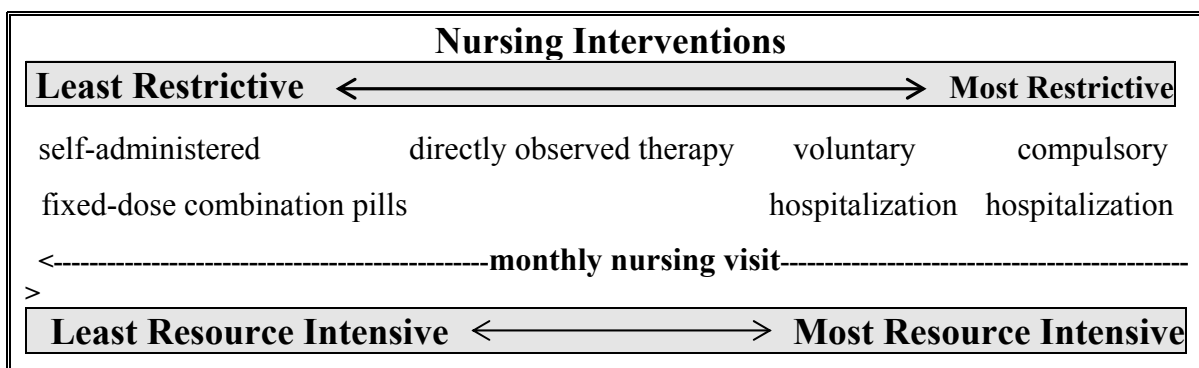
²Commonwealth of Massachusetts Regulations, Standards for Management of Tuberculosis Outside Hospitals, CMR 365:000.

Nursing Case Management Model for Tuberculosis Control



Barriers to Adherence

Personal	Social	Cultural	Health Care System
Age Health (acuity, co-morbidity) HIV Status Alcohol/IDU Health Beliefs Disability Cognitive Function Knowledge	Homeless Occupation Exposure Risk Institutional Living Family Support and responsibilities Other Support systems	Race/Ethnicity TB Stigma Language Attitudes (re: illness) Cultural Health Beliefs	Attitudes(re: system) Norms (re: care-seeking, protection of self and others) Nontraditional Health practices



II. CASE MANAGEMENT STANDARDS OF CARE

Standards of Care: Standards of care and expected outcomes for the management of clinically suspected and confirmed cases of tuberculosis and their contacts include the following:

Suspected/Confirmed Cases of Tuberculosis:

1. The diagnosing health care provider reports potential cases to the Department of Public Health, Division of Tuberculosis Prevention and Control within 24 working hours after suspecting the diagnosis and the Division reports it to the local health department/Board of Health (BOH) within 24 working hours.
2. The local BOH designates a registered nurse as the direct case manager who will work in collaboration with the TSA nurse to manage the suspect/case until closed to supervision.³ This direct case manager may work for the BOH or other community health nursing agency contracted for public health nursing services by the BOH.
3. The direct case manager conducts an initial nursing assessment (case investigation) within three working days after the BOH is notified of the potential case; the optimal standard is an assessment in the hospital and patient's home environment, accompanied by an outreach educator, when appropriate.
4. The direct case manager initiates an individualized nursing care plan and further develops it with input and approval of the case management team. The care plan includes a medical treatment plan that is in accordance with the American Thoracic Society's standards for care.
5. For patients in a health care facility, discharge planning is done in collaboration with the BOH and the Division of Tuberculosis Prevention and Control.
6. The direct case manager performs a monthly nursing assessment at the patient's home, clinic, office, or other mutually agreed upon site.

³ Closed to supervision: Patient completes an adequate and effective course of tuberculosis therapy; moves out of the community; or tuberculosis is ruled out as the diagnosis.

Contacts:

7. The direct case manager initiates the contact investigation within three working days of notification of the potential case, ideally coinciding with the initial case assessment. The direct case manager begins the contact investigation report and sends it to the regional TSA nurse.
8. Evaluation of identified contacts includes a Mantoux tuberculin skin test (Mantoux technique) and referral for a medical evaluation, including a chest radiograph when indicated.
9. Contacts under five years of age are considered for a course of treatment of latent TB infection, regardless of the skin test result.
10. Immunosuppressed contacts are considered for a course of treatment of latent TB infection, regardless of the skin test result.
11. The direct case manager re-tests contacts with an initial negative skin in 8 - 12 weeks. Complete contact investigation report will be completed and send to the regional TSA nurse.

Source Case Investigations:

12. Perform a source case investigation on children under one year of age who have a positive tuberculin skin test.

III. TUBERCULOSIS NURSING CASE MANAGEMENT PROTOCOLS

Case Reporting: Report confirmed and clinically suspected cases to the Massachusetts Department of Public Health, Division of Tuberculosis Prevention and Control within 24 hours of diagnosis on the TB Case/Suspect Reporting Form (# MDPH TB07) or by telephone to the 24-hour toll-free reporting line (1-888-MASS-MTB). The Division sends a copy of the report form to the local health department within 24 hours. The Division immediately telephones the local health department for high-priority reports needing immediate follow-up.

Nursing Case Management Model: The local Board of Health (BOH)/Health Department designates a nurse as the direct case manager. The Tuberculosis Surveillance Area Nurse (TSA) is the indirect case manager, coordinating care with other team members. A case management model uses individual approaches and tools to reach the desired outcomes rather than one standard approach for all patients. Members of the case management team include the patient, the direct case manager, the TSA nurse, the community outreach educator (ORE), and the physician; others may be brought into the team as needed for an individual case, such as a social worker, the clergy, etc.

A. Initial Patient Assessment:

1. Initial Case Investigation

Conduct a case investigation on every confirmed or clinically suspected case of TB reported to the health department, including patients cared for by private providers.

Objectives of case investigation:

1. To establish rapport and trust with the patient.
2. To collect data for the nursing assessment including demographic, medical, environmental, economic and social factors that may influence adherence to the prescribed treatment plan or pose barriers to accessing care.
3. To determine the patient's potential to transmit the TB organism to others and to determine the risk to contacts based on the duration and location of potential exposures.
4. To identify potentially exposed contacts.
5. To provide education about tuberculosis to the patient and/or family.

Preparation for interview:

Before interviewing the patient: 1) contact the physician to be sure the patient has been informed of the diagnosis and what the physician has told the patient; and 2) obtain clinical information regarding skin test results, chest x-ray, laboratory test results, particularly sputum smears and cultures, and other diagnostic test results.

Interview:

- Within three working days, the direct case manager performs the case investigation, including the interview (with an ORE as appropriate).
- The initial interview includes a face-to-face encounter and is optimally done in the patient's home environment and/or hospital, but may occasionally be done at the board of health office.
- During the interview, the nurse provides education in a culturally and linguistically competent manner on the following:
 - diagnosis; transmission; the prevention of TB transmission to others; medication administration; the effects of inadequately treated TB; the importance of completing the prescribed course of treatment (including keeping all appointments); the consequences to the individual if he or she is unwilling to adhere to the treatment plan; and the health care system.
- During the interview, the nurse:
 - collects information including demographic, medical, environmental, economic and social factors that may influence adherence to the prescribed treatment plan or pose barriers to accessing care;
- Begins identifying potentially exposed contacts;
- Performs an HIV risk assessment for patients with unknown HIV status (see Appendix for sample HIV Risk Assessment tool – form # MDPH - TB14).
- Refer patients with risk(s) for HIV counseling and testing.
- After the investigation is completed, the direct case manager completes the TB history form (form # MDPH – TB04B) and sends it to the TSA nurse.

2. Contact Investigation

The goal of a contact investigation is to identify contacts who will benefit from a course of treatment of latent TB infection. The direct case manager conducts an investigation on all persons with pulmonary or laryngeal TB.

Objectives of contact investigation:

1. To identify persons who have been exposed to the presenting infectious case

and who, therefore, are at greater risk of developing tuberculosis infection and disease than is the general population.

2. To perform appropriate testing of identified contacts in a systematic fashion.
3. To ensure access to medical evaluation and treatment of latent TB infection as appropriate for these contacts.
4. When possible, to identify the source of tuberculosis disease transmission, particularly when the presenting case is a child.
5. To identify environmental factors that may be contributing to the transmission of tuberculosis.
6. To ensure medical evaluation, treatment, and follow-up of any additional cases of active tuberculosis identified during the contact investigation.

Contact investigation procedure:

- Use Concentric Circle Analysis theory to set limits and establish priorities for conducting the contact investigation according to the level of exposure.
- Test close contacts with a tuberculin skin test using the Mantoux technique within 7 working days after the presenting case is clinically suspected/diagnosed.
- Obtain nursing histories of contacts to identify risk factors for progression to TB disease, such as immunosuppression, history of previous infection and/or therapy, and/or risk factors for drug resistance.
- Discuss the need to test contacts at worksites, schools, and other institutions with the TSA nurse before notifying the employer, school, or other institution; the Division will provide written testing recommendations according to the Division's Worksite/School/Institution Contact Investigation Protocol.
- For close contacts located in another community, notify that BOH of the need to test the contacts and return the results to you for your records.
- If there is evidence that transmission occurred among the contacts tested (the inner circle), then expand the testing to the next circle of contacts.
- Within 2 weeks, refer for a medical evaluation all infected contacts and the following non-infected contacts: children under five years of age, adolescents and immunosuppressed persons
- Initiate the Contact Report (Epidemiologic Report on a Tuberculosis Case form # MDPH-TB03) and send the first copy with the results of the first round of testing and medical evaluations to the TSA nurse within thirty days.
- Re-test non-infected contacts in eight to twelve weeks.
- Send the final copy of the Contact Report with results of the second round of

- testing and medical evaluations to the TSA nurse within three months.
- Follow up with the physician to verify that infected contacts were offered treatment for latent TB infection, regardless of age.
- Follow up with the physician to verify that contacts who are under five years of age, adolescents, or immunosuppressed persons were offered treatment for latent TB infection, regardless of skin test results.

B. Nursing Care Plan:

The direct case manager initiates the plan and further develops it in collaboration with the TSA nurse and other case management team members.

Objective of the nursing care plan:

To identify interventions that use the least restrictive measures appropriate for the patient and protect the health of the public.

Care plan process:

- Formulate the nursing diagnoses from the data collected by various team members, including the nurse's assessment, the outreach educator's patient interview, and the medical evaluation.
- The team discusses appropriate strategies and tools needed to assist the patient to complete therapy.
- The team discusses the need for ORE involvement.
- The plan includes specific approaches and strategies and identifies the person(s) responsible for implementation; the integration of cultural and ethnic beliefs and health practices; and appropriate regimens based on drug susceptibility data.
- The team accepts the patient care plan.

1. Treatment Plan

Note: Medical treatment is in accordance with the American Thoracic society's recommended treatment regimens. A copy of these recommendations is available from the Division and consultation is available through the TSA nurse or the Division's TB Control Officer. (See Appendix for medication dosage chart - MDPH TB15).

Treatment Principles:

1. All patients in Massachusetts with unknown sensitivities are to start on four drugs (usually isoniazid, rifampin, pyrazinamide, and ethambutol).

2. To obtain optimal blood levels, each medication is usually taken in a single daily dose, not split into multiple doses. (Second-line drugs are usually split into multiple doses.)
3. Patients who are to be on self-administered medications are to be placed on fixed-dose combination pills (rifater initially, and rifamate for the continuation phase).
4. Patients who receive directly observed therapy (DOT) could be placed on twice or thrice weekly intermittent therapy after two weeks of daily therapy.

2. Discharge Plan

Any healthcare institution or correctional facility which plans to discharge a person with confirmed or suspected tuberculosis into the community needs to develop a discharge plan in collaboration with the state TB Division and local health department.

- Discharge planning begins upon admission of the person with confirmed or clinically suspected tuberculosis.
- The institution promptly reports the person to the state health department; the TSA nurse notifies and works with the direct case manager to develop an appropriate discharge plan.
- **Pre-discharge consultation** is required and includes the direct case manager, the hospital discharge planner, and other appropriate team members. Good communication is key to developing an appropriate outpatient treatment plan.
- Hospital providers and the direct case manager participate in and agree upon the discharge plan. Assess patient for any risk factors for non-adherence. Include interventions for appropriate medical, nursing, and community follow-up.
- Infectious persons must not be discharged to a home or other environment until the risk of ongoing transmission to vulnerable persons (e.g. infants, young children or immunosuppressed persons) is minimized.
- A pre-discharge home visit by the direct case manager is **strongly recommended** to evaluate the home environment and potential risk to others.
- Arrange for the patient to have enough TB medications, in hand, until his/her next medical appointment. Prescriptions alone are usually inadequate for the new TB patient (pharmacies may not have drugs, or there may be linguistic and economic barriers).
- Make follow-up appointments prior to discharge.

C. Implementation:

Note: The next section (Treatment Delivery Protocols) provides specific guidelines for the implementation of the patient care plan, including guidelines for the use of self-administered therapy and directly observed therapy.

Objectives:

1. To implement and coordinate the interventions identified in the plan of care.
2. To implement the plan in a safe and appropriate manner consistent with public health laws and regulations.
3. To deliver care by linking the patient with other appropriate service providers.
4. To ensure appropriate delegation of interventions that are to be implemented by other team members.

Implementation of the Medical Plan:

- A physician's order is required to initiate treatment. Drug order changes must be obtained promptly to prevent any interruption in therapy. The direct case manager needs to contact the physician if the patient is started on less than four anti-tuberculous drugs.

3. Outreach Involvement

Availability and assignment of community outreach educators: The Division employs several community ORE targeted to specific high-risk communities or populations who work under the supervision of the TSA nurses. The Refugee and Immigrant Health Program (RIHP) also employs OREs who work with refugee and immigrant populations, particularly persons from Southeast Asia, the former Soviet Union, and other countries with new refugee populations.

- The direct case manager notifies the TSA nurse when the assistance of an ORE is needed. Based on availability and priority, the TSA nurse may assign an ORE.
- The TSA nurse clinically supervises the Division's OREs with clinical backup of the ORE provided by the Assistant Director for Patient Management services or RIHP Coordinator.
- The TSA nurse will assign an ORE to every new suspect/case, when feasible, within 3 working days of notification to visit with the patient and conduct an outreach educator interview.
- The TSA nurse will notify the RIHP for all refugees and immigrants from populations served by the RIHP.

- Optimally, the ORE does the initial interview in a joint visit with the direct case manager during the initial case investigation.
- The ORE is responsible for documenting and reporting any patient complaints or change in the patient's condition to the direct case manager.

Priorities for Outreach Educator Assignments: The following persons are the highest priority for the assignment of an ORE:

Suspects/Cases:

- requiring DOT
- admitted to the Tuberculosis Treatment Unit at Lemuel Shattuck Hospital
- with drug resistance, especially multidrug resistant tuberculosis
- with a history of or risk factors for non-adherence, including previous TB
- who are class A/B immigrant arrivals
- under eighteen years of age

Contacts on Treatment for latent TB infection:

- exposed to multidrug resistant tuberculosis cases
- under eighteen years of age, particularly under five years

Although these groups are the highest priority, the following persons on treatment for latent TB infection may also be a priority for the assignment of an ORE:

- refugee/immigrant arrivals (within 5 years) to the United States from high prevalence countries
- children, particularly under 5 years of age
- persons discharged from a correctional institution
- immunosuppressed persons

4. Referrals for Other Community Resources as Needed

- Link the patient with other appropriate service providers to address the total needs of the patient (i.e. fuel assistance, social services, counseling).

D. Evaluation:

The direct case manager evaluates the patient monthly in a face-to-face encounter for clinical response, adherence to therapy, and possible adverse reactions to the medications.

Objectives:

1. To re-evaluate the patient care plan and revise as necessary.

2. To evaluate the patient's clinical response to therapy and prevent the development of drug resistance, adverse reactions, or further morbidity.

1. Monthly Evaluation by the Direct Case Manager:

- Assess for a response to therapy as indicated by clinical improvement and sputum conversion. Collect sputum weekly until conversion; induce sputum if necessary. **A physician's order is not needed to collect sputum.**
- Assess for any signs of adverse drug reactions through patient interviews and periodic laboratory tests (liver function tests, basic audiometry, visual acuity screening, etc.).
- **At each patient encounter**, check for adherence to the treatment plan through patient interviews.
- For persons on self-administered therapy, test the urine for INH metabolites at each patient encounter and observe urine for the presence of rifampin.
- When an ORE is assigned to the patient, the direct case manager and the ORE need to communicate on a regular basis regarding the patient's progress.
- Contact the patient's physician to monitor the patient's progress.
- Consult with the case management team regarding the use of more restrictive measures if patient is non-adherent with the treatment plan, such as the use of incentives and enablers, ORE involvement, directly observed therapy, voluntary hospitalization, and compulsory (involuntary) hospitalization. This consultation may result in revising the plan.
- Complete a TB clinic Case/Suspect Follow Up Form (form # MDPH – TB05) or nursing notes for each encounter. Document assessment of clinical status and adverse reactions, all teaching and instructions to the patient, and any changes to the treatment plan.
- A Drug-O-Gram (form # MDPH – TB09) can be used to evaluate the adequacy of the treatment regimen, especially in drug resistant cases or cases whose treatment requires a change from the standard drug regimen.

Note: Patients who have interrupted therapy for more than two consecutive weeks may need to have their length of therapy re-evaluated and may need to restart treatment from the beginning after consultation with the physician.

2. Division of Tuberculosis Prevention and Control Evaluation Plan:

Division staff reviews newly confirmed and suspected cases and contact investigations initially at monthly review conferences. Division staff retrospectively reviews confirmed cases at six-month intervals until the end of treatment.

IV. TREATMENT DELIVERY PROTOCOLS

Treatment Standard of Care: Evaluate every suspected case of tuberculosis for the need for directly observed therapy (DOT) based on an assessment of risk factors for non-adherence. For patients on therapy for TB disease without any known risk factors for nonadherence, the Division recommends self-administered therapy, using fixed-dose combination pills (rifater for the initial phase and rifamate for the continuation phase) as the standard of care.

Completion of adequate therapy is the responsibility of the case management team. The method of treatment delivery (i.e. self-administered or directly observed therapy) is the team's decision.

Candidates for Directly Observed Therapy: The following persons are to receive DOT:

- patients with a prior history of non-adherence/incomplete TB treatment;
- patients with a previous episode of TB;
- patients with drug resistant tuberculosis disease, especially resistance to two or more drugs;
- patients unwilling, or unable, to follow prescribed treatment regimens;
- patients discharged from the Tuberculosis Treatment Unit (TTU) at Lemuel Shattuck Hospital (LSH) on treatment;
- children under eighteen years of age with tuberculosis disease;
- patients with a history in the past year of: substance abuse, homelessness or incarceration;
- patients with a recent history of mental illness;
- contacts to multi-drug resistant cases who are on treatment for latent TB infection;
- contacts under five years of age who are on treatment for latent TB infection.

A. Guidelines for Self Administered Therapy:

Self-administered therapy is the ingestion of prescribed anti-tuberculosis medication by the patient.

1. Initiate Treatment

- Self-administered therapy is best done on a daily basis; the use of fixed-dose combination drugs can only be done daily as the dosage is not amenable to twice/thrice weekly administration. **A specific physician's order is required to initiate fixed-dose combination pills.**
- Give the patient only a one-month supply of medication.

- Consider incentives, enablers, the use of community outreach educators and/or a patient contract (see sample letter in forms section) to assist the patient through treatment.
- Consider providing a pillbox to assist the patient in taking the medications correctly. If they are used, consult the pharmacist to ensure appropriate labeling of the box. An alternative is for the health care worker to oversee the patient pouring the medications into the box compartments.

2. Educate Patient

- Provide appropriate written instructions and oral education to the patient regarding his/her treatment and follow-up in a culturally and linguistically competent manner.
- Reinforce education at every encounter with the patient.

3. Evaluation

The direct case manager evaluates the patient monthly in a face-to-face encounter for clinical response, adherence to therapy, and possible adverse reactions to the medications.

Medication Monitoring:

- Assess for any signs of adverse drug reactions through patient interviews and periodic tests (liver function tests, basic audiometry, vision disturbances, etc.).
- Tell patient to discontinue medications and report the symptoms when there are indications of adverse reactions. Consult with the physician immediately.

Clinical Response to Therapy:

- Assess for response to therapy as indicated by clinical improvement and sputum conversion. Collect sputum weekly until conversion; induce sputum collection, if necessary. **A physician's order is not needed to collect sputum.**
- Consult with the physician if patient fails to improve.

Adherence to Therapy:

- **At each patient encounter**, check for adherence to the treatment plan through patient interviews and test the urine for INH metabolites and observe the urine for the presence of rifampin.
- If the patient fails to keep an appointment, attempt contact by phone. If the patient cannot be reached by phone, make a home visit within 24 hours.
- If nonadherence is suspected or patient cannot be located, notify TSA nurse.

B. Guidelines for Directly Observed Therapy (Dot):

Directly Observed Therapy (DOT) is the direct observation, by a health care provider or other designated responsible person, of the ingestion of prescribed anti-tuberculosis medication by the patient. Observation by a family member is not considered DOT.

Directly Observed Therapy (DOT) Procedure:

- The direct case manager implements DOT with input from other members of the case management team (physician, ORE, TSA Nurse/RIHP). The direct case manager advises the patient that a health care worker will observe each dose of medication. Depending on resources, an ORE may be available to assist the direct case manager in providing DOT.
- DOT may be done exclusively by the direct case manager or may be a shared responsibility between the direct case manager and an ORE.
- **A physician's order is not required to initiate daily DOT.**
- DOT is best done on a twice weekly or thrice weekly intermittent dosing routine. **An intermittent dosing regimen does require a physician's orders.**
- For patients receiving DOT daily, allow the patient to self-administer medications on the weekend (ensure that a weekend supply of medication is available), unless it appears the patient is unable or unwilling to take medication safely and reliably, in which case, arrangements for weekend DOT will be necessary. On Monday discuss the previous weekend's self-administered therapy with the patient, test the urine for INH metabolites and observe the urine for the presence of rifampin and document adherence indicators.
- Attempt to schedule a mutually agreeable time and place for DOT. Tailor the DOT site and time to meet the needs of the patient. Listen to and validate patient concerns regarding DOT.
- Consider using a patient contract (see sample letter in forms section) and/or incentives.
- If DOT is scheduled on-site at the clinic or health department, minimize the waiting time.
- If the patient fails to keep an appointment, attempt phone contact. If the patient cannot be reached by phone, make a home visit within 24 hours. If unable to locate or if the patient misses one week of treatment, notify the TSA Nurse. Document indications of nonadherence (missed clinic/DOT appointment, not at home when nurse or ORE visits).
- If DOT is scheduled at the patient's home, leave the medications in the patient's home. When the nurse/ORE arrives for DOT, if the patient states he/she already took the medications, or there is other evidence that the medication count is incorrect, consider keeping the medications at health department in the original medication bottles. The nurse/ORE picks up the

bottles from the health department before each visit to the patient. An alternative solution is to supply a locked box for the medications, which is left in the patient's home (one key is kept by the direct case manager and one by the ORE).

- If the patient is not available for DOT, do not leave the medications at the home.
- Record each observed dose of medication on a medication sheet or the DOT Log (form # MDPH – TB11)
- Document all teaching and instructions to the patient. Complete a TB clinic Follow Up Form (form # MDPH – TB05 or MDPH – TB06) or nursing notes for each encounter.
- Periodically re-evaluate the need for continuation of DOT. Re-evaluation of the treatment delivery method may indicate a change to lesser or more restrictive measures.

C. Guidelines for Long-term Hospitalization:

Admission to the Tuberculosis Treatment Unit (TTU) is reserved for persons with confirmed or clinically suspected tuberculosis who cannot or should not be managed in the outpatient setting. The admission may be voluntary or involuntary.

1. Voluntary hospitalization

- Voluntary hospitalization is appropriate for persons with complex medical, psychosocial, and infection control management problems.
- If patient agrees to a voluntary hospitalization, the direct case manager consults with the TTU Medical Director for admission and explains the TTU environment to the patient.

2. Involuntary (compulsory) hospitalization

- Involuntary hospitalization or confinement may be necessary when there is documented nonadherence to the prescribed treatment plan for tuberculosis, or the patient is unable to follow the treatment plan and the public's health is threatened as a result.
- Employ less restrictive measures before imposing measures that are more restrictive.
- The direct case manager needs to document failed attempts at using least restrictive nursing interventions (DOT, incentives, and enablers). (See M.G.L. c.111, Section 94A for involuntary commitment procedures).
- If the admission is involuntary, follow the procedures set forth in M.G.L. c.111, Sections 94A through 94C. Use less restrictive measures first, and give the

patient the opportunity for voluntary admission prior to involuntary admission.

Guidelines for Treatment of Latent TB Infection:

Priorities for Treatment of Latent TB Infection:

The persons who benefit most from treatment of latent TB infection are those at highest risk of developing active disease once infected. Priorities for nursing case management of persons on treatment for latent TB infection are listed below:

- contacts to multi-drug resistant tuberculosis cases;
- children under five years of age who are close contacts;
- infected close contacts (of a known or suspected infectious case of TB disease)
- persons with Class A/B Immigrant status;
- persons with an abnormal chest x-ray consistent with old inactive TB;
- infected children under five years of age;
- infected non-US born persons here less than five years;
- persons with current or past history of substance abuse, mental illness, homelessness, or incarceration;
- HIV infected persons;
- persons with medical conditions that predispose them to active TB (i.e. insulin dependent diabetes mellitus, renal failure, gastrectomy, silicosis).

1. Initiate Treatment of Latent TB Infection

- Treatment of latent TB infection is best done on a daily basis; the use of twice-weekly directly observed treatment of latent TB infection (DOPT) may be used for at-risk adults and children who cannot or will not reliably self-administer therapy. The priorities for DOPT are contacts under five years of age and contacts to multi-drug resistant TB cases (see Guidelines on Directly Observed Therapy for the procedure).
- Give the patient only a one-month supply of medication (**see below for two-month regimen**).
- A pillbox may be used to assist the patient in taking the medications correctly. If a pillbox is used, consult the pharmacist to ensure appropriate labeling of the box. An alternative is for the health care worker to oversee the patient pouring the medications into the box compartments.

2. Educate Patient

- Provide appropriate written instructions and oral education to the patient regarding the medication and follow-up in a culturally and linguistically competent manner.

- Reinforce education at every encounter with the patient.

3. Evaluation

- Evaluate the patient monthly in a face-to-face encounter for adherence to therapy and possible adverse reactions to the medications (**see below for two-month regimen**).
- Assess for any signs of possible adverse drug reactions through patient interviews. Routine baseline and follow-up laboratory monitoring can be eliminated in most persons with latent TB infection, except for those with HIV infection, pregnant women (or those in the immediate postpartum period), persons with chronic liver disease or those who use alcohol regularly.
- Tell patient to discontinue medications and report the symptoms when there are indications of adverse reactions. Early signs of hepatitis include anorexia and malaise. Consult with the physician.
- If the patient develops symptoms of active disease while on treatment, immediately refer the patient for a medical evaluation.
- **At each patient encounter**, check for adherence to the treatment plan through patient interviews, and test the urine for INH metabolites or rifampin.
- If the patient fails to keep monthly appointments, attempt contact by letter or phone.
 - For low-risk individuals, after three failed clinic appointments, document efforts, and close out patient's record.
 - For high-risk individuals, the use of other strategies may be needed to assist the patient through treatment, such as different regimens, incentives, enablers, or community outreach educators.
- Completion of therapy is based on total number of doses administered – not on duration of therapy alone.
- Complete nursing notes or a TB clinic Preventive Therapy Follow Up Form (form # MDPH – TB06) for each encounter.

Two-month Regimen of Rifampin (RIF) and Pyrazinamide (PZA)

- No more than a 2-weeks supply of RIF/PZA should be dispensed at a time to facilitate periodic clinical assessments.
- Evaluate the patient at two, four and six weeks of treatment in a face-to-face encounter for adherence to treatment, tolerance, and possible adverse reactions and at eight weeks to document completion of treatment.
- At each encounter, instruct patients, in a language they understand, to stop taking RIF/PZA immediately and seek medical consultation if symptoms develop.
- Document therapy completion on clinic Preventive Therapy Follow-Up form.
- Completion of therapy with the RIF/PZA regimen is defined as taking 60 doses of the prescribed medications within a three-month period.

least restrictive

most restrictive

self-administered fixed-dose combination pills

DOT

voluntary hospitalization

compulsory hospitalization

<-----monthly nursing visit----->

Incentives/enablers as appropriate

Directly Observed Therapy: Directly observed therapy (DOT) by the ORE and/or nurse, depending on resources and clinical status of patient. The nurse will encourage the physician to order twice/thrice weekly therapy when appropriate.

Compulsory Hospitalization: Involuntary hospitalization due to continued demonstrated nonadherence to therapy. Less restrictive measures must be tried first and compliance with procedures required by State regulations.

V. CONTACT EVALUATION AND MANAGEMENT

Theoretical Framework: Contact investigation or tracing identifies those persons who are at greatest risk of having been infected with TB by the index or presenting case and who are at high risk for progression to disease. Successful contact tracing requires skills in patient assessment, interviewing, counseling, and evaluation.⁴ The Concentric Circle Approach is the standard method of investigation used for contact tracing. This method provides a systematic approach for setting limits and establishing priorities for testing based on the risk of tuberculosis transmission to the identified contacts.

Analysis of the results of the contact investigation is important in determining the need for further testing based on the actual risk of tuberculosis transmission that has occurred. Use the Concentric Circle Analysis tool (see Figure 2) to calculate rates of actual transmission in contacts exposed to the index case in different settings. Rates of infection higher than expected in any of the settings indicate a need to expand the testing to the next circle of contacts with less exposure.

Legal Authority: 105 CMR 365.200, section C.4 provides the legal authority for the investigation and reporting of contacts to the Massachusetts Division of Tuberculosis Prevention and Control.

A. **Transmission Risk Assessment:**

Identifying the appropriate contacts to test can be a difficult process as there are many variables to consider that may affect your decisions. Begin by assessing the infectiousness and potential for transmission of each suspected and confirmed case of tuberculosis when initiating the contact investigation. Collect information regarding **person** (characteristics of the suspect case and contacts), **place** (potential exposure sites and their characteristics), and **time** (duration of exposure) **factors** to determine the priority and extent of the contact investigation. Evidence that transmission has occurred will impact your decisions regarding who to test or when to expand the limits of the contact investigation.

1. **Person Factors**

Person factors include clinical characteristics of the suspect case that indicate the case's infectiousness and potential to transmit infection, as well as clinical factors associated with the contact's immune response - the contact's probability of becoming infected. Cases with a high likelihood of transmission are those who have laryngeal or pulmonary disease, a productive cough, an acid-fast bacteria

⁴ Boutotte, J. and Etkind, S. "Community-Based Strategies for Tuberculosis Control" in Tuberculosis: A Sourcebook for Nursing Practice," Cohen, F., and Durham, J., Eds. Springer Publishing Co., NYC. pp. 180-181.

(AFB)-positive sputum smear (spontaneous specimen), lung cavitation, and who are not on anti-tuberculous medications. Those with a lower probability of transmission have extrapulmonary disease, AFB-negative sputum smears, no lung cavities, are not coughing, or have been on anti-tuberculous medications for at least two weeks. Factors to be considered in evaluating a contact's susceptibility include immune status, especially immunosuppression due to HIV disease, and the possibility of previous infection.

2. Place Factors

Place factors include the environment of the potential exposures. Evaluate the potential for exposure in each of the three sections of the Concentric Circle: home, work or school, and leisure activities (see Figure 2). **In some circumstances, exposure outside the home may be as high or higher than in the home, and contact testing will need to be done there, independent of the contact investigation results within the home.**

Place factors also include the characteristics of the physical environment, such as the size of rooms (volume of air), ventilation, number of persons in the room and presence or absence of sunlight or ultraviolet lighting.

3. Time Factors

Time factors include the potential duration and frequency of exposure of the contacts to the case. Prolonged exposure is normally needed for transmission to occur. However, the length of exposure needed for a case to transmit the bacteria to a contact is impacted by the infectiousness of the case, the contact's immune system, and the environmental characteristics. To determine the length of possible exposure, consider the case's date of onset of symptoms, especially the cough. The highest potential for transmission to occur is from this time until the case is on adequate treatment for at least two weeks, is clinically improving, and has three negative sputum smears.

4. Evidence of Transmission

To determine if transmission has occurred consider the level of infection (number of infected contacts without a known history of a positive tuberculin skin test), infection in young children, documented skin test conversions, and secondary cases of disease. If there is evidence of transmission, you may need to expand the circle of contacts to test until there is no further indication of exposure.

B. Priorities for Contact Investigation:

As discussed in section 'A', contact investigations are prioritized according to the characteristics of the (confirmed or suspected) TB case, the characteristics of the contact, the environment, and the duration of exposure. Contacts to individuals who have sputum smear-positive pulmonary or laryngeal tuberculosis are at highest risk to become infected with *M. tuberculosis*. Evaluate a contact if the known or suspected case has the following characteristics:

- 1) sputum or laryngeal specimen smear-positive for AFB
- 2) negative sputum or laryngeal AFB smear, but positive *M. tuberculosis* culture
- 3) other respiratory specimens AFB smear or culture-positive
- 4) negative cultures for *M. tuberculosis*, but cavitory chest x-ray ⁵
- 5) definite clinical evidence of active pulmonary TB and actively coughing, but AFB smears and/or cultures were not obtained prior to the initiation of anti-tuberculous treatment *

Contact investigations are not recommended for extra-pulmonary cases. A source case investigation may be indicated for a child less than five years of age diagnosed with extra-pulmonary tuberculosis disease to seek the infectious source patient who infected the child.

C. Evaluation and Management of Contacts:

1. Symptom Review

Contacts with tuberculosis symptoms have priority over all other contacts.

- Immediately evaluate for TB disease contacts who have symptoms consistent with tuberculosis: obtain a chest x-ray and sputum specimen for smear and culture and administer a tuberculin skin test. If indicated, evaluate for extra-pulmonary sites of disease.
- Classify and report contacts with tuberculosis symptoms as TB suspects, regardless of the chest x-ray findings and tuberculin skin test reactions.

2. Initial Tuberculin Skin Test and Follow Up

Test all close contacts of an individual who has an AFB-positive sputum smear or a positive *M. tuberculosis* culture for tuberculosis infection with a tuberculin skin test (TST), unless they have documentation of a previous positive TST reaction. All close contacts identified are to be listed on the Contact Report (Epidemiologic Report on a Tuberculosis Case form # MDPH-TB03).

⁵Contact investigation for persons with negative or unknown sputum cultures is not routinely recommended, provided there are no other relevant clinical or exposure factors, indicating a need for testing.

Contacts with a documented previous positive reaction need a chest x-ray only if they have symptoms suggestive of tuberculosis or are immunosuppressed or have other medical risk factors.

- If the reaction to the initial TST is positive (≥ 5 mm), the contact needs a chest x-ray.
 - ~ If the chest x-ray is abnormal, immediately evaluate the contact for tuberculosis disease.
 - ~ If the chest x-ray is normal, evaluate the contact for treatment of latent TB infection.
- In some instances, an individual may state that he or she has a past positive TST reaction. If it is not possible to verify this information, you may repeat the TST (unless the person describes a “very large” reaction the size of a quarter or larger to a previous TST).
- Complete the first copy of the Contact Report (Epidemiologic Report on a Tuberculosis Case form # MDPH-TB03) and send to the regional TSA office.

3. Repeat Tuberculin Test and Follow Up

- If the reaction to the initial TST is negative (< 5 mm), a repeat TST should be given eight to twelve weeks after the contact’s last exposure to the case, while the case was infectious.
 - ~ **During the window period between the two TSTs, the following contacts should have a chest x-ray to rule out tuberculosis disease and start preventive treatment, even if the TST is negative (Window Prophylaxis):**
 - 1) contacts under five years of age;
 - 2) contacts between five and fifteen years of age, at the physician’s discretion;
 - 3) contacts who are HIV seropositive or otherwise immunosuppressed;
 - 4) contacts with known risk factors for HIV infection who decline HIV testing.
- If the initial TST for a contact is not done until eight weeks after the contact’s last exposure to the case (while infectious), and the reaction is negative (< 5 mm), a repeat TST is not indicated.
- If the reaction to the repeat TST is positive (≥ 5 mm), the contact needs a chest x-ray (if one has not already been done).
 - ~ If the chest x-ray is abnormal, immediately evaluate the contact for tuberculosis disease.

- ~ If the chest x-ray is normal, evaluate the contact for treatment of latent TB infection.
- If the reaction to the repeat TST is negative (< 5mm) and the individual **is no longer in close contact with an infectious patient**:
 - ~ For immunocompetent contacts (including children), no follow-up is necessary. Discontinue prophylaxis treatment, if started initially.
 - ~ For most close contacts who are HIV seropositive or have known risk factors for HIV infection, but decline HIV testing, a full course of treatment of latent TB infection is indicated, regardless of the TST reaction. Anergy testing has no role in the evaluation of contacts.
- If the reaction to the repeat TST is negative (< 5mm) and the individual **remains in close contact with an infectious patient**, continue treatment if he or she:
 - 1) is under five years of age;
 - 2) is between the ages of five and fifteen, at the physician's discretion;
 - 3) is HIV seropositive or otherwise immunosuppressed; or
 - 4) has known risk factors for HIV infection, but declines HIV testing.
- ~ Repeat the TST every three months for uninfected contacts who remain in close contact with an infectious case.
- Complete the second copy of the Contact Report (Epidemiologic Report on a Tuberculosis Case form # MDPH-TB03) and send to the regional TSA office. A sample letter is provided in the Forms section that can be used to obtain contact testing and follow-up data done by private providers.

4. Contact Evaluation for Patients whose Cultures Convert Back to Positive

In some instances, a tuberculosis patient's cultures may convert to negative and then become positive again. This may happen if a patient is lost to follow-up and discontinues his or her medication before completing treatment, or if treatment was not adequate.

- If the patient is found after a treatment lapse of three months or longer and his or her cultures have become positive again, or if the patient relapses while on treatment after becoming culture negative, a second window period needs to be defined and the patient needs to be re-interviewed.

- ~ Re-evaluate contacts identified during the initial investigation if they were exposed again.
- ~ Test and evaluate any new contacts identified.

D. Special Considerations for Infant and Child Contacts:

Infants and children under five years of age who live in the same household as an infectious tuberculosis patient may need to be removed from the home setting (or hospitalize the patient) until one of the following conditions is met:

- The infectious patient has been on appropriate effective tuberculosis chemotherapy for at least two weeks and has demonstrated a clinical response to treatment (e.g., decreased cough and fever, resolving lung infiltrates, a consistent decrease in the numbers of organisms on sputum AFB smears) or has three consecutive negative sputum smears, at least 24 hours apart.⁶
- The child has started treatment of latent TB infection (including window prophylaxis).

1. Initial Tuberculin Skin Test and Chest X-ray for Infants

All infant contacts need to receive an initial TST and both a posterior-anterior and a lateral chest x-ray.

- If the chest x-rays are normal, start the infant on window prophylaxis treatment of latent TB infection, even if the TST reaction is negative ($< 5\text{mm}$). Isoniazid is used for infant contacts of patients with isoniazid-susceptible tuberculosis disease; rifampin can be used for contacts of patients with isoniazid-resistant but rifampin-susceptible tuberculosis disease. Consider multi-drug preventive treatment with medications other than isoniazid and for infant contacts to patients with multi-drug resistant disease (resistant to at least isoniazid and rifampin).
 - ~ Breast-feeding is not contraindicated when the mother is being treated for latent TB infection, but the infant should receive supplemental pyridoxine.
 - ~ The amount of isoniazid provided by breast milk is inadequate for treatment of the infant.
 - ~ If the reaction to the initial TST was positive ($\geq 5\text{ mm}$), the infant needs to complete a full course (9 months) of treatment of latent TB infection.

⁶Department of Public Health, Reportable Diseases and Isolation and Quarantine Requirements, CMR 105.

- If the chest x-rays show hilar adenopathy (with or without a pulmonary infiltrate), refer the infant for diagnosis and treatment, even if the TST reaction is negative (< 5 mm). Consultation with a pediatric pulmonologist may be indicated to evaluate the cause of hilar and/or mediastinal lymphadenopathy. Early morning gastric aspirates may be indicated to obtain specimens for diagnostic purposes.

2. Repeat Tuberculin Skin Test and Chest X-ray for Infants

All infant contacts with a negative reaction to the initial TST should have a repeat TST at three to four months of age and again at six months of age. (Infants younger than six months old may be anergic.)

- If the reaction to the repeat TST converts to positive (≥ 5 mm), the infant needs both a **posterior-anterior and a lateral chest x-ray**. If the chest x-rays are normal, continue the treatment for a total of 9 months.
 - ~ If the chest x-rays show hilar adenopathy (with or without a pulmonary infiltrate), refer the infant for diagnosis and treatment. Early morning gastric aspirates may be indicated to obtain specimens for diagnostic purposes.
- If the reaction to the repeat TST is negative (< 5 mm) and the chest x-rays are normal, treatment of LBTI may be discontinued if the exposure has ended (the source case is on anti-tuberculosis treatment and has consistently negative tuberculosis cultures). If the contact is younger than six months old, continue treatment of latent TB infection until six months of age because an infant's immune system is not fully developed and may not mount a response to the TST.

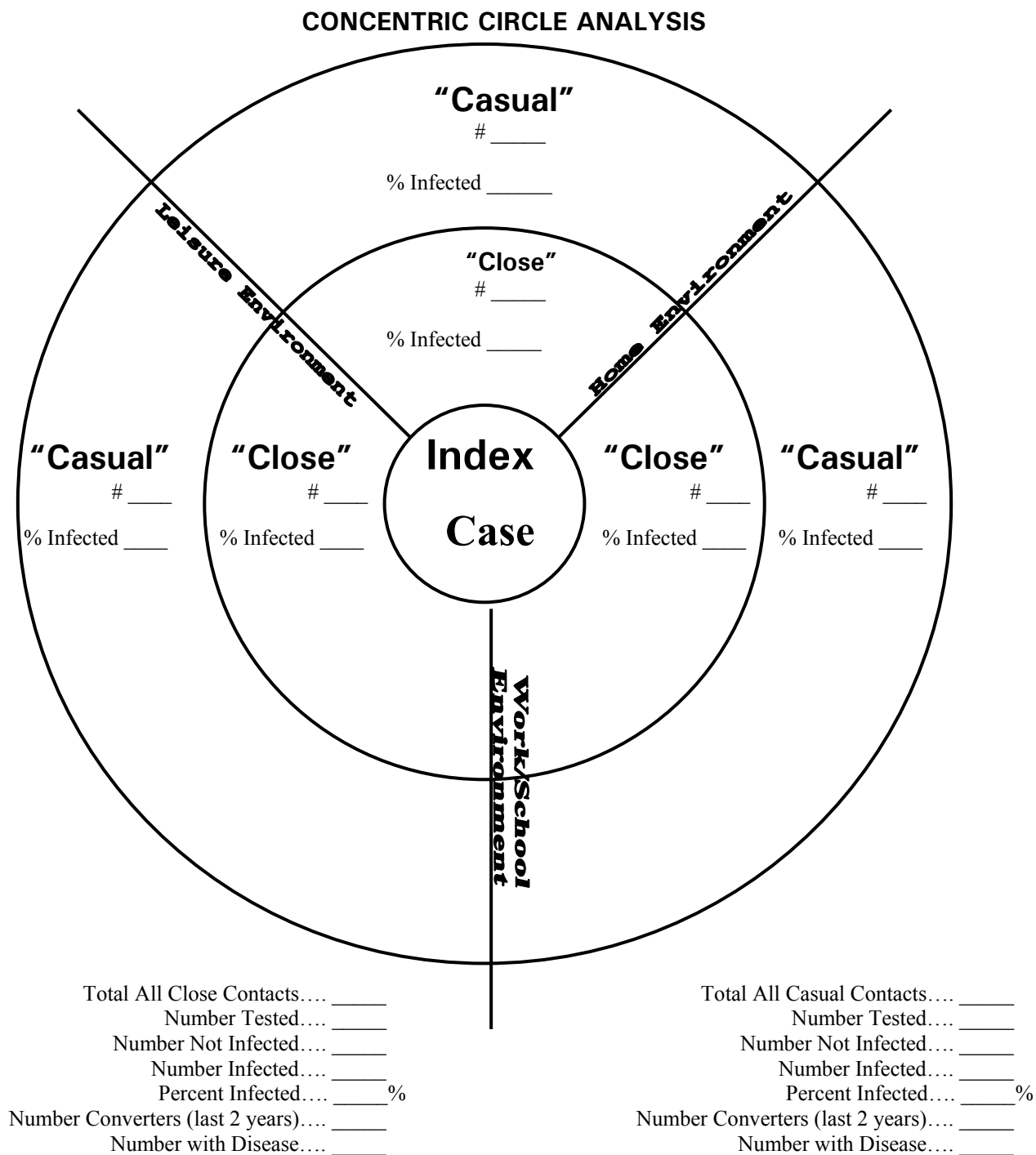
Source Case Investigation

The Massachusetts Division of Tuberculosis Prevention and Control recommends that a source case investigation be done for all children under 1 year of age found to have TB infection and who have not been identified as a contact to a known case of tuberculosis (see Appendix MDPH TB16 for policy and procedure). The possible source patient is usually an adult in the home, or an adult with whom the child spends significant periods of time (e.g., friends, relatives, baby sitters, daycare personnel, etc.)

Possible Source Patient who is Symptomatic

Promptly evaluate for disease any possible source patient who has symptoms suggestive of tuberculosis, by obtaining a chest x-ray, collecting three consecutive daily sputum samples for AFB smear and culture, and administering a TST.

Figure 2



Close contacts are not just household contacts; they can also be work, school, and leisure contacts. Conversely, not all household contacts are necessarily close contacts. Figure adapted from the Mississippi State Dept. of Health's form.

VI. GLOSSARY OF TERMS⁷

Adherence: The willingness and/or ability of patients to maintain responsibility for following the treatment plan by taking anti-tuberculous medications as prescribed and by keeping necessary health care appointments.

Case Investigation/Case Assessment: The investigation conducted by the local Health Department/Board of Health designated nurse to determine the potential the patient has to transmit disease to others, the risk of infection for contacts based on level and duration of exposure, and the medical, environmental, economic and social factors which may influence adherence to the prescribed treatment plan.

Clinically Suspected Case of Tuberculosis ("Suspect"): A condition in which the individual has acid fast bacilli (AFB) in the sputum or other body fluid or tissue as evidenced by a laboratory smear; or has chest x-ray or other diagnostic findings interpreted as probable tuberculosis by a qualified medical authority.

Confirmed Case of Tuberculosis ("Case"): Refers to meeting the criteria as set forth by the federal Centers for Disease Control and Prevention (CDC) to verify a case as tuberculosis disease (See Reporting Section of Clinic Manual for Case Definition).

Contact: An individual that has shared the same indoor airspace with a person with communicable tuberculosis disease for a sufficient amount of time so that there is a probability that transmission of tuberculosis has occurred.

Contact Investigation: The procedure of tracing, testing and evaluating persons who have been in contact with a person with potentially infectious tuberculosis.

Course of Therapy: A complete course of therapy is defined as ingesting a minimum of 80% or more of the recommended amount of doses (for self-administered therapy, complete therapy can be assumed if the patient picked up 100% of the prescribed refills and there were no indications of nonadherence observed).

Direct Case Manager: a registered nurse, designated by the local board of health, who has the overall responsibility for initiating, coordinating, implementing, and evaluating the patient's treatment plan until the completion of therapy. The nurse case manager also assists the patient in accessing other community resources, such as social services, that will assist him or her with adherence to therapy.

⁷Commonwealth of Massachusetts Regulations, Standards for Management of Tuberculosis Outside Hospitals, CMR 365:004 Definitions.

Directly Observed Therapy (DOT): The direct **observation**, by a health care provider or other designated responsible person, of the **ingestion** of prescribed anti-tuberculous medication by the patient. **Observation by a family member is not considered DOT.**

Enablers: A term used to describe anything that assists (enables) the patient to more readily complete therapy or access the treatment delivery system. Enablers include providing transportation, bus fares, flexible clinic hours, etc.

Incentives: Something that motivates a patient to take his or her medication, keep clinic appointments or assist him or her to complete therapy. Incentives include food coupons, food or coffee at the clinic, cash or any individualized gift or reward for adhering to the treatment plan.

Outreach Educator (ORE): An individual who has been specifically trained by the Division of Tuberculosis Prevention and Control and/or the Refugee and Immigrant Health Program (RIHP) to assist with TB case management services to priority patients. The outreach educator also provides social support and advocacy for individuals in a culturally competent manner.

Self-Administered Therapy: Self-administered therapy is the ingestion of prescribed anti-tuberculous medication by the patient.

Source Case Investigation: The procedure of tracing, testing and evaluating contacts to identify the source of tuberculosis disease transmission to the presenting case or an infected individual. This is particularly important for children under five years of age.

Tuberculosis Surveillance Area (TSA) Nurse: A Public Health Nursing Advisor who works for the Division of Tuberculosis Prevention and Control and is responsible for coordinating tuberculosis activities in a designated geographic region of the state.

VII. COMMONWEALTH OF MASSACHUSETTS REGULATIONS

105 CMR 350.000: Determining Active Tuberculosis

Section

- 350.001: Purpose
- 350.002: Authority
- 350.003: Citation
- 350.100: Determination

350.001: Purpose

105 CMR 350.000 establishes procedures for determining the existence of active tuberculosis.

350.002: Authority

105 CMR 350.000 is adopted under the authority of M.G.L. c. 111, §§ 3 and 94A through 94H.

350.003: Citation

105 CMR 350.000 shall be known, and may be cited as 105 CMR 350.000: *Determining Active Tuberculosis*.

350.100: Determination

A) Sufficient evidence of active communicable tuberculosis shall be based upon one of the two indicators below:

- 1) A laboratory report of sputum or other bodily fluid or tissue found to contain tubercle bacilli, as evidenced by culture or other definitive diagnostic test, or suspected to contain tubercle bacilli as evidenced by smear.
- 2) Chest x-ray findings interpreted as active tuberculosis by a qualified physician may be used as evidence for active tuberculosis when it is not possible to have a laboratory report showing a positive smear and/or positive culture or other definitive diagnostic test for the tubercle bacilli.

B) When tubercle bacilli have thus been found or suspected, the individual shall be considered to have active communicable tuberculosis until the following criteria are met:

- 1) The individual receives an adequate and complete course of tuberculosis drug therapy as defined by the American Thoracic Society guidelines and three successive cultures of specimens collected at intervals of one week, or other definitive diagnostic test, shall demonstrate no tubercle bacilli, or
- 2) Until clinical or laboratory evidence leads to a diagnosis other than tuberculosis.

Regulatory Authority

105 CMR 350.000: M.G.L. c. 111, §§ 3 and 94A through 94H.

**105 CMR 360.000: Tuberculosis Treatment Unit
Standards for Admission, Treatment and Discharge**

Section

- 360.001: Purpose
- 360.002: Authority
- 360.003: Citation
- 360.004: Definitions
- 360.100: Designation
- 360.200: Admissions
- 360.300: Treatment Standards
- 360.400: Discharge

360.001: Purpose

105 CMR 360.000 sets forth the standards of admission, treatment, and discharge of tuberculosis patients to and from the State Designated Tuberculosis Treatment Unit.

360.002: Authority

105 CMR 360.000 is adopted under the authority of M.G.L. c. 111, §§ 3, 5, 6, 77, 79 and 94D.

360.003: Citation

105 CMR 360.000 shall be known, and be cited as the *Standards of Admission, Treatment and Discharge of Tuberculosis Patients in the State Designated Tuberculosis Treatment Unit*, 105 CMR 360.000.

360.004: Definitions

Acid Fast Bacilli: Organisms that retain certain stains even after being washed with acid alcohol. Most are mycobacteria. When seen as stained smear of sputum or other clinical specimen, a diagnosis of tuberculosis should be considered.

Adherence: The willingness and/or ability of patients to maintain their share of the responsibility for their therapy by taking their anti-tuberculosis medications as prescribed and by keeping the necessary health care appointments.

Clinically Suspected Tuberculosis: A condition in which the individual has acid-fast bacilli in the sputum or other bodily fluid or tissue as evidenced by a laboratory smear; or has chest x-ray findings interpreted as probable tuberculosis by a qualified medical authority.

Communicable: The ability to transmit disease from one person or animal to another.

Confirmed Case of Tuberculosis: "Confirmed Case" refers to meeting the criteria as set forth by the federal Centers for Disease Control and Prevention (CDC) to verify a case as tuberculosis disease.

Division of Tuberculosis Control or Division: The program within the Department of Public Health, which administers the provisions of 105 CMR 360.000.

Drug Resistant Tuberculosis: Tuberculosis caused by tubercle bacilli that are unresponsive to one or more anti-tuberculosis drugs.

Tubercle Bacillus/Bacilli: A bacillus (bacteria) causing tuberculosis; usually refers to *Mycobacterium tuberculosis*.

360.100: Designation

The Division of Tuberculosis Control has the responsibility for designating/contracting with a treatment facility for a specialized Tuberculosis Treatment Unit and shall be responsible for the supervision and control of admissions, treatment and discharges. Authority for the management of persons with tuberculosis or clinically suspected tuberculosis, admissions and discharges may be delegated to the treatment facility through contractual agreement and/or written policy.

360.200: Admissions

- A) Admission to the Tuberculosis Treatment Unit (TTU) is reserved for persons with a confirmed case of tuberculosis or clinically suspected tuberculosis who cannot or should not be managed in the outpatient setting. The primary admission reasons are as follows:
- 1) Continued inability or unwillingness to abide by proper medical treatment for confirmed or clinically suspected tuberculosis in a

communicable form. The admission may be voluntary or involuntary. If the admission is involuntary, the procedures set forth in M.G.L. c. 111, §§ 94A through 94C shall be followed. Least restrictive measures shall be used first, and the patient shall be given the opportunity for voluntary admission prior to an involuntary admission.

2) Complex medical management problems that require the close supervision of an inpatient setting. These include, but are not limited to: Persons with drug resistant disease or persons with progressive tuberculosis disease that are not improving with outpatient management; persons with toxic reactions to therapy; and persons with concurrent illnesses which interfere with or prohibit successful outpatient treatment of tuberculosis.

3) Persons with a confirmed case of tuberculosis or clinically suspected tuberculosis, in a communicable form, who have living arrangements in congregate settings where respiratory isolation is not possible and the public health is endangered.

B) Boards of health, hospitals or other health care providers who initiate the admission process shall review the appropriateness and the procedure for the admission with the medical director of the TTU or with his/her designee.

C) The TTU shall send the Division of Tuberculosis Control written notification of all accepted admissions within five days of admission. The Division of Tuberculosis Control shall also receive from the designated TTU written notification of all requests for admission that were denied within five days of this denial. The information required in such notifications shall be determined by the Division of Tuberculosis Control.

D) The TTU is responsible for billing third-party payors and for seeking insurance benefits for those who are eligible for such benefits. The Commonwealth is the payor of last resort; however, no patient shall be denied care and treatment for tuberculosis because of inability to pay.

360.300: Treatment Standards

A) Medical treatment for tuberculosis shall be according to the current standards set forth by the federal Centers for Disease Control

and Prevention (CDC) and the American Thoracic Society (ATS) or other qualified medical authority.

B) Appropriate services for concurrent medical and psychosocial problems which affect adherence to proper medical care for tuberculosis shall be part of the patient treatment plan.

360.400: Discharge

A) Discharge planning shall involve the TTU staff and other health care providers within the treatment facility, the Division of Tuberculosis Control, the local board of health from the community where the patient did or will reside, and other appropriate community agencies. The designated discharge planner for the TTU shall be responsible for consulting with the necessary personnel from the treatment facility, the Division of Tuberculosis Control, and appropriate community agencies and shall arrange for discharge planning meetings. The Division of Tuberculosis Control shall ensure that the appropriate local board of health personnel are involved in the discharge plan.

B) Multi-disciplinary health care provider conferences shall be held at least monthly to review patient progress and discharge plans.

C) The TTU shall notify the Division of Tuberculosis Control three days prior to the discharge of the patient. The TTU shall also report this discharge, in writing, within five days after the discharge.

D) Within two weeks after the discharge, the appropriate staff of the TTU shall prepare and send admission, treatment and discharge data (as determined by the Division of Tuberculosis Control) to the Division of Tuberculosis Control and the local health departments for the purposes of data analysis and program planning.

Regulatory Authority

105 CMR 360.000: M.G.L. c. 111, §§ 3, 5, 6, 77, 79 and 94D.

105 CMR 365.000: Standards for Management of Tuberculosis Outside Hospitals

Section

- 365.001: Purpose
- 365.002: Authority
- 365.003: Citation
- 365.004: Definitions
- 365.100: Public Health Precautions
- 365.200: Case Management
- 365.300: Medical Care and Follow Up
- 365.400: Tuberculosis Infection Management
- 365.500: Notification
- 365.600: Discharge of Tuberculosis Patient into Outpatient Treatment

365.001: Purpose

The purpose of 105 CMR 365.000 is to protect the public health through standards for outpatient management of tuberculosis. The objectives are to enhance treatment adherence, to provide clinical monitoring, to insure completion of therapy through public health case management and to describe the responsibilities and requirements for case reporting.

365.002: Authority

105 CMR 365.000 is adopted under the authority of M.G.L. c. 111, §§ 3, 5, 6, 7, 18, 81, 94H, 95 and c. 111D, § 6.

365.003: Citation

105 CMR 365.000 shall be known, and may be cited, as 105 CMR 365.000: *Standards for the Management of Tuberculosis (TB) Outside Hospitals*.

365.004: Definitions

Acid Fast Bacilli: Organisms that retain certain stains even after being washed with acid alcohol. Most are mycobacteria. When seen as stained smear of sputum or other clinical specimen, a diagnosis of tuberculosis should be considered.

Adherence: The willingness and/or ability of patients to maintain their share of the responsibility for their therapy by taking their anti-tuberculosis medications as prescribed and by keeping the necessary health care appointments.

Case Assessment: The investigation conducted by the local board of health nurse to determine the potential the patient has to transmit disease to others, the risk of infection for contacts based on level and duration of exposure, and the medical, environmental, economic and social factors which may influence adherence to the prescribed treatment plan.

Clinically Suspected Tuberculosis: A condition in which the individual has acid-fast bacilli in the sputum or other bodily fluid or tissue as evidenced by a laboratory smear; or has chest x-ray findings interpreted as probable tuberculosis by a qualified medical authority.

Communicable: The ability to transmit disease from one person or animal to another.

Confirmed Case of Tuberculosis: "Confirmed Case" refers to an individual who meets the federal Centers for Disease Control and Prevention (CDC) requirements to verify a case of tuberculosis disease.

Contact: An individual that has shared the same airspace with a person with communicable tuberculosis for a sufficient amount of time so that there is a probability that transmission of tuberculosis has occurred.

Contact Investigation: The procedure of tracing, testing and evaluating persons who have been in contact with a patient with potentially infectious tuberculosis.

Division of Tuberculosis Control or Division: The program within the Department of Public Health, which administers the provisions of 105 CMR 365.000.

Droplet Nuclei: The microscopic airborne particles of aerosolized sputum, which can carry tubercle bacilli to the lungs of susceptible individuals.

Drug Resistant Tuberculosis: Tuberculosis caused by tubercle bacilli that are unresponsive to one or more anti-tuberculosis drugs.

Enablers: A term used to describe anything that helps the patient to more readily access the treatment delivery system. These include: providing transportation, bus fares, helping to obtain a driving license, etc.

Incentives: “Motivators”: or something which motivates a patient to take his or her medication, keep clinic appointments or do anything else that is necessary to ensure completion of therapy. Incentives include food coupons, cash or any individualized gift or reward for adhering to the treatment plan.

Nurse Case Manager: A registered nurse, designated by the local board of health, who has the overall responsibility of monitoring and coordinating the implementation of the patient’s treatment plan until the completion of therapy. The nurse case manager also assists the patient in obtaining other community resources, such as social services, that will assist him or her with adherence to therapy.

Tubercle Bacillus/Bacilli: A bacillus (bacteria) causing tuberculosis; usually refers to *Mycobacterium tuberculosis*.

Tuberculosis Infection: Condition in which living tubercle bacilli are present in an individual, without producing clinically active disease. The infected individuals usually have a positive tuberculin skin test but are not infectious.

Tuberculosis Surveillance Area (TSA) Nurse: A Public Health Nursing Advisor who works for the Division of Tuberculosis Control and is responsible for all tuberculosis activities in a designated regional geographic area of the state.

365.100: Public Health Precautions

A) The period of infectivity for tuberculosis is defined in 105 CMR 300.200: *Isolation and Quarantine Regulations*. 105 CMR 300.200 determines when health care providers may discontinue isolation precautions and when individuals with confirmed or clinically suspected tuberculosis may resume community activities and

community living. This includes, but is not limited to, resuming employment, school attendance, shelter living or other residential living arrangements.

B) Outpatient facilities (including but not limited to, hospital outpatient departments, clinics and medical office buildings where active tuberculosis cases are seen for treatment) shall follow current national and local infection control guidelines for the isolation of individuals who are excreting tubercle bacilli into the room air and who may be infectious to others.

365.200: Case Management

A) Case management for tuberculosis is defined as the coordination of the necessary medical, nursing, outreach and social service systems which ensure that all persons with confirmed and clinically suspected tuberculosis are started on appropriate therapy, and that all persons with confirmed tuberculosis complete an appropriate and effective course of treatment.

B) The Division of Tuberculosis Control shall assign regional Tuberculosis Surveillance Area (TSA) Nurses, as necessary, to work cooperatively and in consultation with local board of health authorities and the nurse case manager, designated by the local board of health, to ensure that a case management system is in place for every confirmed or clinically suspected case of tuberculosis.

C) The following measures are a requirement of the case management system:

1) The case shall be reported to the Massachusetts Department of Public Health, Division of Tuberculosis Control, as required by 105 CMR 365.500.

2) All persons with confirmed or clinically suspected tuberculosis shall have a nurse case manager designated by the local board of health who will work in consultation and cooperation with the regional TSA nurse, as necessary, to manage persons with confirmed or clinically suspected tuberculosis. This case management is required regardless of the source of health care (public or private) and the ability to pay for the services or medications.

- 3) In consultation with the treating health care provider, the nurse case manager, designated by the local board of health, determines that a medical treatment plan is in place and is in accordance with the American Thoracic Society (ATS) and federal Centers for Disease Control and Prevention (CDC) standards for care.
- 4) The initial case assessment and contact investigation by the local board of health shall begin within three working days of notification of a potential case of tuberculosis. Contacts to the case shall be identified and categorized for their risk of tuberculosis infection as determined by their level of exposure and the person's potential for generating air-borne tubercle bacilli (droplet nuclei). Contacts shall be investigated according to the ATS/CDC standards and the policies of the MDPH, Division of Tuberculosis Control. Contact investigation reports shall be prepared and given to the TSA nurse for the region, according to the policies developed by the Division of Tuberculosis Control.
- 5) Starting with the first visit to a potential case by the nurse designated by the local board of health, there shall also be an assessment of whether there are factors that affect adherence with therapy. This includes, but is not limited to: poor access to health care facilities; homelessness; work schedules; poverty; language barriers; cultural beliefs; substance abuse; mental health status; recent immigration; and medical conditions which may interfere with treatment. (Complete guidelines are available from the Division of Tuberculosis Control).
- 6) An individualized nursing care plan shall be developed by the local board of health's designated nurse case manager and, depending upon the identified risk factors for non-adherence to therapy, the plan shall include the following:
 - a) A plan to remove barriers to adherence through: enablers which increase access to care; incentives which motivate persons to remain on appropriate therapy; and referrals to community agencies and providers which can assist with identified psychosocial or medical problems.
 - b) Educational services to the individual who has confirmed or clinically suspected TB. The topics include, but are not limited to, the following:
 1. how TB is spread
 2. how to prevent the spread of TB
 3. how to take medications

4. the effects of TB if not adequately treated
 5. the importance of completing the prescribed course of treatment
 6. the patient's responsibility in curing his or her own disease
 7. the consequences to the individual if he or she is unwilling to adhere to the treatment plan
 8. causes of drug resistant TB and its effects
- c) The number of nursing and outreach worker visits and the level of social support shall depend upon the assessed level of adherence to therapy and medical status.
 - d) Directly Observed Therapy (DOT) by medical/ nursing/ outreach caregivers or other individuals identified by the local board of health shall be employed when there is an identified risk to continued adherence to therapy.
 - e) Voluntary hospitalization/ institutionalization in the case of person with complex medical, psycho-social, and infection control management problems.
 - f) Involuntary hospitalization or confinement may be necessary when there is documented non-adherence to the appropriate medical follow-up and treatment for tuberculosis, and the public health is threatened as a result of this non-adherence. Least restrictive measures shall be employed before more restrictive measures are imposed. (See M.G.L. c. 111, § 94A for involuntary commitment procedures)

365.300: Medical Care and Follow-Up

A) All persons with confirmed or clinically suspected tuberculosis shall have an identified medical doctor, qualified and licensed to practice medicine, or a nurse practitioner licensed to practice in the expanded role under the supervision of a qualified medical doctor, to provide medical supervision.

Medical treatment for tuberculosis shall be according to the current standards set forth by the federal Centers for Disease Control and Prevention (CDC) and the American Thoracic Society (ATS), or other qualified medical authority, for chemotherapy and follow-up. The Division of Tuberculosis Control shall make these standards available and provide consultation regarding appropriate therapy when necessary.

B) Providers responsible for medical management of persons with confirmed or clinically suspected tuberculosis disease shall work in cooperation with the local board of health and the Division of Tuberculosis Control for the purposes of case management as outlined in 105 CMR 365.200.

C) Providers must also notify the local board of health in the town where the patient resides and the Division of Tuberculosis Control, of any person with confirmed or clinically suspected tuberculosis in a communicable form, who is unable or unwilling to receive proper medical care and, as such, poses a threat to the public health.

365.400: Tuberculosis Infection Management

Management and treatment of persons infected with tuberculosis, but without active disease, shall be provided in accordance with the current standards set forth by the CDC/ATS or other qualified medical authority.

365.500: Notification

Any health care provider, laboratory, board of health, office of administration of a city, state or private institution or hospital who has knowledge of a case of confirmed tuberculosis or clinically suspected tuberculosis, as defined in 105 CMR 365.004, shall notify the Division of Tuberculosis Control within 24 hours. Upon receipt of such notice, the Division of Tuberculosis Control shall notify the local board of health within 24 hours. Cases involving residents of the City of Boston having confirmed or clinically suspected tuberculosis shall be reported to both the Department and to the Boston Department of Health and Hospitals within 24 hours. This notice shall include the case name, date of birth, age, sex and address.

365.600: Discharge of Tuberculosis Patient Into Outpatient Treatment

Any acute or chronic care hospital or any other institution which provides health care to residents, including but not limited to: prisons; jails; residential treatment centers; nursing homes and rest homes, which plan to discharge a person with confirmed or clinically suspected tuberculosis into the community for outpatient tuberculosis

treatment, shall do discharge planning in collaboration with the State Division of Tuberculosis Control.

The Division shall be notified of such persons with confirmed or clinically suspected tuberculosis, upon his or her admission to the hospital or institution, in order to begin the process for the development of the outpatient case management plan.

The Division of Tuberculosis Control shall notify and work with the local board of health nurse responsible for case management.

A pre-discharge conference regarding case management shall be held and shall include the designated board of health case manager, the TSA nurse from the Division of Tuberculosis Control, as necessary, as well as the discharge planner and medical providers. A plan for appropriate medical, nursing and community agency follow-up shall be made prior to discharge into the community.

Regulatory Authority

105 CMR 365.000: M.G.L. c. 111, §§ 3, 5, 6, 7, 18, 81, 94H, 95; c. 111D, § 6.

**DEPARTMENT OF PUBLIC HEALTH
DIVISION OF TUBERCULOSIS CONTROL**

PROCEDURE FOR COMPULSORY HOSPITALIZATION

Compulsory hospitalizations include a short-term 15-day observation period and a long-term court commitment under the authority of Massachusetts General Laws (MGL), chapter 111, section 94-A, 94-B and 94-C. Regulations supporting the law are 105 CMR 350.000, 360.000 and 365.000.

The designated inpatient Tuberculosis (TB) Treatment Center is located at Lemuel Shattuck Hospital, in a single treatment unit called the Tuberculosis Treatment Unit (TTU).

**94 - A: Local Certification Requesting Hospitalization of Tuberculosis Patient
for Fifteen Days Observation in the Tuberculosis Treatment Center.**

Local Board of Health Responsibilities:

1. "Local Certification" form filled out by appropriate petitioner as allowed by law (board of health, health director, member of board of health or two physicians).
2. The regional Tuberculosis Surveillance Area (TSA) nurse from the Division of Tuberculosis Control advises the petitioner(s) regarding the required documentation. For the City of Boston, where a TSA nurse is not assigned, this advice is given by the Director of Prevention, Policy and Clinical Services, or designated professional staff.
3. There must be laboratory evidence (positive AFB smear /positive TB Culture) and/or chest x-ray findings consistent with active tuberculosis in a communicable form. For clarity, the laboratory evidence should contain the first and last positive smear/culture reports as well as the first and last negative smear/culture reports. Included in the chest x-ray reports should be those with the worst findings as well as those that are stable or improving.
4. There must be clear evidence that the patient is unable or unwilling to accept proper medical treatment. This should include dates of outpatient treatment attempts and dates when the patient failed to keep scheduled appointments. Least restrictive measures, such as incentives and enablers, which help patients adhere to treatment, outreach worker involvement, and directly observed therapy (DOT) are examples of outpatient treatment attempts. Regulation 105 CMR 365.200

describes in further detail the case management system that ensures least restrictive measures.

5. The "Local Certification" form is notarized and sent with the attached documentation reports to the Division of TB Control.

6. In an emergency situation when the "Local Certification" information needs to be processed as soon as possible by the Division of TB Control, permission may be granted to send the notarized form first by fax and then by delivery. In these instances, it is necessary to review the request with the Director of Prevention, Policy and Clinical Services (or designee).

State TB Control Responsibilities:

1. The "Local Certification" form is reviewed by the Director of Prevention, Policy and Clinical Services, or designee, for appropriate documentation. This information is summarized in the State 94-A form called "Order for Admission for Fifteen Days' Observation to State Tuberculosis Treatment Center".

2. The Administrative Assistant, or designee, for the Division of TB Control types the following:

a). The summary, prepared by the Director of Prevention, Policy and Clinical Services (or designee), from the "Local Certification" onto the three State 94-A (yellow) forms.

b). The form authorizing the local police department to transport the patient to the State TB Treatment Center (Lemuel Shattuck Hospital).

3. All three of the completed 94-A forms, and the police form must be signed by the Commissioner of the Department of Public Health or his/her designee (usually the Assistant Commissioner / physician in the Bureau of Communicable Disease). A Notary Public must witness the signing and notarize the 94-A forms. The Director of Prevention, Policy and Clinical Services, or designated professional staff, will be available for questions and review of the completed forms.

4. The Administrative Assistant, or designee, makes 2 copies of the original "Local Certification" papers, the attached documentation reports and the police form. The following folders are then prepared:

a). Folder labeled with the name of the original petitioners (e.g. Health Department) containing one signed original 94-A form, an attached copy of the

"Local Certification" with the documentation reports, and a copy of the police authorization form.

b). Folder labeled Lemuel Shattuck Hospital containing one signed original 94-A form, an attached copy of the "Local Certification" with the documentation reports, and the original police authorization form.

c). Folders (a) and (b) (above) are either picked up by or sent to the local petitioner, depending upon how quickly the signed forms are required by the petitioner, in order to proceed with the hospitalization. The petitioner keeps a folder for the local records and the other folder labeled "Lemuel Shattuck Hospital" is sent with the patient to this hospital. The police authorization form, contained in this folder, is presented to the police escort.

d). A red colored folder, labeled with the patient's name, remains with the Division of Tuberculosis Control and contains the original "Local Certification", with the documentation reports, attached to a signed original 94-A form and a copy of the police authorization form.

e). For admissions from areas outside of Boston a copy of the "Local Certification" form is sent to the regional TSA nurse.

5. The Director of Prevention, Policy and Clinical Services, or designee, reviews the procedure for admission to Lemuel Shattuck Hospital TTU with the local petitioner. The petitioner is advised to contact the Medical Director of the TTU and review patient information prior to admission.

94 - B: Hospital Application for Transfer of Tuberculosis Patient to the State Tuberculosis Treatment Center for Fifteen Days' Observation.

1. Hospitalized patients, with evidence of active tuberculosis in a communicable form, who indicate their desire to leave the hospital against medical advice, may (pending approval) be transferred directly to the Tuberculosis Treatment Unit (TTU) at Lemuel Shattuck Hospital for a 15 day observation period.

2. Calls from hospitals to the Division of Tuberculosis Control regarding a potential 94-B admission are directed to the Director of Prevention, Policy and Clinical Services, or designee. The caller is advised of the following:

a). There must be laboratory evidence (positive AFB smear/positive TB culture) and/or chest x-ray findings consistent with active tuberculosis in a communicable form.

b). The Medical Director, or designee, of the TTU has the authority to approve admissions for the TTU.

c). Once the decision is made to detain the patient for a 15 day observation period, the hospital administrator must transfer the patient to Lemuel Shattuck Hospital or detain the patient at his/her own institution. If the patient does not go to Lemuel Shattuck Hospital, the administrator of the hospital, where the patient is detained, must immediately petition the courts for a prolonged hospital stay under the authority of Massachusetts General Laws Chapter 94-C.

d). Forms for documenting the need for a 94-B admission are available through the Division of TB Control and may be faxed to the referring hospital.

3. Weekend and off-hour calls are referred to the Medical Director (or designee) of the TTU at Lemuel Shattuck Hospital for approval and admission.

4. Patients admitted to Lemuel Shattuck Hospital on a voluntary basis are also subject to the rules of MGL, Chapter 111, Section 94-B, if he/she indicates a desire to leave against medical advice and would subsequently become a threat to the public health. In these instances, the medical director (or designee) of the TTU needs to contact the Office of the General Counsel and ask the attorney assigned to Lemuel Shattuck Hospital to petition the court as required under MGL Chapter 111, Section 94-C. (See below). The patient is then detained until the court hearing.

94 - C: Court Orders for Long-Term Hospitalization of Uncooperative Tuberculosis Patient to the State Tuberculosis Treatment Center

1. Under the following conditions long-term court orders may be necessary for patients who are currently being detained for a 15-observation period under the authority of 94-A or 94-B:

a). The patient continues to be unable or willing to accept proper medical care and this can be clearly documented in the patient record or through the testimony of health care workers who have made treatment attempts.

b). The court must be petitioned by the end of the 15 day observation period at Lemuel Shattuck Hospital TTU, or immediately in the case where another hospital chooses to detain a patient under the authority of 94-B.

2. Two physicians must examine the patient and report the evidence that he/she is unwilling or unable to accept proper care and thereby poses a serious danger to the public health.
3. The DPH Counsel for Lemuel Shattuck Hospital may ask for the testimony of other health care workers who have documentation and/or knowledge of the patient's inability or unwillingness to accept proper care.
4. Due process for the patient includes a right to counsel.
5. The judge may assign a specific time frame for commitment (usually until treatment is finished); however, the patient has the right to another hearing 6 months from the original hearing (section 94-G).
6. The patient may be discharged from the hospital prior to the completion of treatment if Lemuel Shattuck Hospital, in collaboration with the Division of TB Control and the local board of health, determines that it is in the best interest of the patient and the public health (section 94-F).

Telephone for Division of TB Control:

(617) 983-6970
(617) 983-6990 - FAX

Telephone for Lemuel Shattuck Hospital TTU:

(617) 971-3352

LOCAL CERTIFICATION

(For Hospitalization as Uncooperative Tuberculosis Patient)

We

.....
.
(Board of Health - Health Director - **Member of Board of Health** - or two physicians duly licensed to practice medicine in the Commonwealth) as subscribers, being severally and duly sworn, do make oath and depose as follows:

We find thatDate of Birth.....

residing at

.....
(street and no.) (city or town)

County of**Commonwealth of Massachusetts** is:

- (1) afflicted with active tuberculosis, and
- (2) is unwilling or unable to accept proper medical treatment, and
- (3) is thereby a serious danger to the public health

H__ therefore should be committed to the State Sanatorium Treatment Center as required by Sections 94A and 94C of Chapter 111 of the General Laws. We hereby refer h__ to the Commissioner of Public Health for further examination in accord with the above law.

The above findings of the subscribers are based on the following facts:

(1) Evidence of active tuberculosis in a communicable form:

(a) Laboratory findings: (specify and attach report)

(b) Chest X-ray findings: (specify and attach report)

(c) Other facts:

(2) Outpatient treatment efforts made prior to plans for involuntary confinement: (Specify treatment attempts and enablers such as outreach worker assignments, directly observed therapy, social and psychiatric support systems, and incentives to receive appropriate care.)

(over)

(3) Inability or unwillingness to abide by proper medical treatment for tuberculosis in a communicable form and thereby a serious threat to the public health: (Include dates of appointments not kept as well as supporting evidence that the individual will not accept appropriate care.)

OTHER

Brief description of pertinent medical and psycho-social problems: (Include date of tuberculosis diagnosis and probable duration, other relevant medical conditions, current living arrangements, household members, a list of children and their ages, and patient's occupation.

.....
(Petitioner)

Subscribed and sworn to before me on thisday of20

.....
(Notary or Justice of the Peace)

Forms supplied by: Mass. Dept. of Public Health, Bureau of Communicable Disease Control
Division of Tuberculosis Control
305 South Street
Jamaica Plain, MA 02130

EPIDEMIOLOGIC REPORT ON A TUBERCULOSIS CASE

Date received in TSA office:

Case name: _____
 Last First
 Specimen Source: _____
 Case Smear Status: _____ Culture: _____
 Case CXR Results: _____
 Person Completing Form: _____
 Telephone #: (____) _____
 Date Worksheet Started: ____/____/____

Return this form to:

Exposure Setting Codes:

- [01] – Household [09] – Other - specify
 [02] – Non-household/Friends/Relatives [10] – Unknown
 [03] – Restaurant/Bar [11] – Other Worksite
 [04] – Correctional Facility
 [05] – School/Day Care
 [06] – Nursing Home
 [07] – Shelter
 [08] – Hospital/Acute Care

Contact #1 _____ DOB: ____/____/____
 Last First
 AGE: ____
 Address City Exposure Setting Code: ____
☐ Male ☐ Female Country of Birth: _____
 Relationship: Contact is the _____ of the case. **Comments:**

Mantoux Tests		
Date Administered		
Results in mm		

CXR		
Date	Normal	Abnormal
		<input type="checkbox"/> Noncav <input type="checkbox"/> Cav

Treatment		
START	____/____/____	
END	____/____/____	
INH		
RIF/PZA		
Other		

Contact #2 _____ DOB: ____/____/____
 Last First
 AGE: ____
 Address City Exposure Setting Code: ____
☐ Male ☐ Female Country of Birth: _____
 Relationship: Contact is the _____ of the case. **Comments:**

Mantoux Tests		
Date Administered		
Results in mm		

CXR		
Date	Normal	Abnormal
		<input type="checkbox"/> Noncav <input type="checkbox"/> Cav

Treatment		
START	____/____/____	
END	____/____/____	
INH		
RIF/PZA		
Other		

Contact #3 _____ DOB: ____/____/____
 Last First
 AGE: ____
 Address City Exposure Setting Code: ____
☐ Male ☐ Female Country of Birth: _____
 Relationship: Contact is the _____ of the case. **Comments:**

Mantoux Tests		
Date Administered		
Results in mm		

CXR		
Date	Normal	Abnormal
		<input type="checkbox"/> Noncav <input type="checkbox"/> Cav

Treatment		
START	____/____/____	
END	____/____/____	
INH		
RIF/PZA		
Other		

Contact #4 _____ DOB: ____/____/____
 Last First
 AGE: ____
 Address City Exposure Setting Code: ____
☐ Male ☐ Female Country of Birth: _____
 Relationship: Contact is the _____ of the case. **Comments:**

Mantoux Tests		
Date Administered		
Results in mm		

CXR		
Date	Normal	Abnormal
		<input type="checkbox"/> Noncav <input type="checkbox"/> Cav

Treatment		
START	____/____/____	
END	____/____/____	
INH		
RIF/PZA	____ P	
Other		

Contact #5 _____ DOB: ____/____/____
 Last First
 AGE: ____
 Address City Exposure Setting Code: ____
☐ Male ☐ Female Country of Birth: _____
 Relationship: Contact is the _____ of the case. **Comments:**

Mantoux Tests		
Date Administered		
Results in mm		

CXR		
Date	Normal	Abnormal
		<input type="checkbox"/> Noncav <input type="checkbox"/> Cav

Treatment		
START	____/____/____	
END	____/____/____	
INH		
RIF/PZA		
Other		

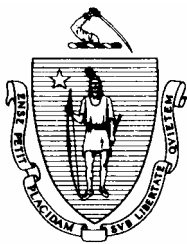
For office use only

TBID Number: _____

Date received in SLI office: _____

Reviewed by Epidemiologist _____

6/2000 FORMMDPH - TB03 Routing: Pink Copy after 1st screening - TSA Nurse White copy after second screening – TSA nurse - MDPH; Blue Copy - Local Health Department



JANE SWIFT
GOVERNOR

ROBERT P. GITTENS
SECRETARY

HOWARD K. KOH, MD, MPH
COMMISSIONER

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
State Laboratory Institute
305 South Street, Jamaica Plain, MA 02130
(617) 983-6200

Bureau of
Communicable
Disease Control

Date: _____

Dear Dr. _____:

The patient(s) listed on the attached sheet have been identified as close contacts to an infectious case of Tuberculosis (TB). They plan to contact your office to schedule an evaluation.

Adults and Children 5 Years of Age and Older: The Division of TB Prevention and Control of the Massachusetts Department of Public Health recommends that contacts age 5 and older receive a Mantoux PPD skin test and, when indicated, a medical evaluation (including a chest radiograph). All persons with a positive skin test (≥ 5 mm) should be placed on treatment of latent TB infection.

Infants and Children Less Than 5 Years of Age: Young children under 5 years of age should immediately receive a medical evaluation. This includes: a Mantoux PPD skin test, a thorough physical examination to rule out active pulmonary or extrapulmonary TB, chest radiographs (bilateral and anterior-posterior), and prophylaxis with INH, even if the skin test result is negative. If the repeat skin test (done 8 to 12 weeks later) is negative, prophylaxis can be discontinued. If positive, then a full course of treatment of latent TB infection (a total of 9 months of INH) should be prescribed.

Massachusetts regulations (105 CMR 365.200, section C.4) provide the local health department with the legal authority to investigate and report contacts to the Division. The results of the testing and medical follow-up of close contacts referred for medical examination are sent to the Division and reported in aggregate to the Centers for Disease Control and Prevention.

Please complete the enclosed form and return by mail or fax to:

Public Health Nurse's Name: _____

Local Health Department Address: _____

Local Health Department Fax: _____

Yours truly,

_____, RN

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

DIVISION OF TUBERCULOSIS PREVENTION AND CONTROL

TB RECORD # _____

INITIAL CLINICAL EVALUATION FORM

Hospital I.D.: _____ S.S.# (If known): _____

NAME, LAST: _____ FIRST: _____

D.O.B.: ____/____/____ Sex: M ____ F ____

City: _____ Zip Code: _____

Phone: (____) _____ ☐ None

Country of Birth: ☐ U.S. ☐ Other: _____

Date of Visit: ____/____/____

☐ TB Clinic: _____

Type of Visit: ____ A₁ (MD Visit-with x-ray)
____ A₂ (MD Visit-with no x-ray)

Date of Visit: ____/____/____

☐ Private Provider: _____

Address: _____

Phone: (____) _____

CLINICAL DATA: Weight: _____

Previous X-ray Done: ☐ No ☐ Yes - Where: _____

CHEST X-RAY: Date: ____/____/____ ☐ Not Done

Results: ☐ Normal ☐ Cavitary ☐ Abn/Non-Cavitary ☐ Unknown

CXR Status: ☐ Stable ☐ Improving
☐ Worsening ☐ Unknown



Brief description of findings: _____

BACTERIOLOGY: ☐ No Bacteriology Pending

Source: _____ Date Collected: ____/____/____

Smear Result: ☐ Neg ☐ Pos ☐ Pending ☐ Not Done

Culture Result: ☐ Neg ☐ Pos ☐ Pending ☐ Not Done

Pathology: ☐ Pathology Done ☐ No Pathology Done

Source: _____ Date Collected: ____/____/____

Results: _____

EVALUATION:

ATS Classification:

____ (0) No TB exposure, not infected ____ (3) Active TB disease, current

____ (1) TB exposure, not infected ____ (4) Old TB disease, not current

____ (2) TB infection, no disease ____ (5) Suspected disease, diagnosis pending

Disease Site(s): (Class 3 or 5) ☐ Pulmonary ☐ ExtraPulmonary: _____

HIV Risk Assessment: ☐ Not Done ☐ Done at Clinic ☐ Done prior to Clinic

HIV Risk Identified: ☐ Yes ☐ No

☐ Referred for Counseling & Testing ☐ Declined Counseling & Testing

PRESCRIBED MEDICATIONS: To Start on ____/____/____

Expected Duration of Therapy: ____ Months

DRUG	DOSAGE	FREQ	ACTUAL DATE STARTED
Rifater (RFT)			
Rifamate (RFM)			
INH			
RIF			
PZA			
EMB			

COMPLETE THE FOLLOWING PLAN:

☐ Baseline ALT: _____ ☐ WNL ☐ ABNL ☐ Not Done/Ordered

☐ Reason Treatment of Latent TB Infection not recommended:

☐ Pregnant - Return after Delivery ☐ ABN ALT ☐ Previous Therapy

☐ Other: _____

☐ Patient Declined Treatment of Latent TB Infection

☐ Discharged from Clinic/No further Follow-Up Recommended

☐ Baseline Eye Check for EMB: ☐ WNL ☐ ABNL ☐ Not Done

Sputum Ordered: ☐ Yes ☐ No

Other Tests Ordered: _____

☐ Potential for Adherence to Treatment Assessed

☐ Self-Administered Therapy (No risk factors for non-adherence)

OR

☐ Directly Observed Therapy: ☐ Daily ☐ Intermittent: ____ X/Week

Person(s) performing DOT: _____

DOT scheduled at: ☐ Clinic ☐ BOH ☐ Home ☐ Other: _____

Patient Education: (Check all that apply)

☐ TB Infection vs. disease explained ☐ S&S of disease

☐ Medication risks/benefits explained ☐ Importance of taking meds

☐ Importance of keeping appointments ☐ Literature given to patient

☐ Case/Suspect Reported to Division

Toll-Free Reporting Number: 1-888-MASSMTB (627-7682)

Next Visit: ____/____/____

☐ Interpreter needed next visit: Language: _____

COMMENTS: _____

Signature: ☐ M.D. _____ Signature: ☐ R.N. _____

Instructions for the Initial Clinical Evaluation Form

General Instructions: The purpose of this form is to document information on the patient's initial clinical evaluation visit. This form is only completed for the **initial visit**. Subsequent visits are documented on the Preventive or Case/Suspect Follow Up forms, as appropriate. **Please print legibly.**

These instructions address areas that may not be self-explanatory or have special instructions. Please fill form out as completely as possible. **Areas that are required are specifically noted in these instructions. In general, required fields are bolded (excluding the section titles).**

TB Record #: Leave blank. The Division completes this upon data entry.

Identification demographics (left top box): Printing is faint, so addressographs can be used.

All bolded fields in this section are required. Hospital I.D.: Hospital or clinic ID or record number, when applicable.

Clinic Visits: 'Date of Visit', 'TB Clinic name', and 'Type of visit'. **Required.**

OR

Private Provider: Date of Visit and Provider name. **Required.**

Clinical Data and Bacteriology: Results and dates required. There are boxes for 'Not Done' and 'Unknown' results for chest x-rays and bacteriology. Results of chest X-rays and bacteriology should be ascertained and documented before submitting form. The chest diagram is optional for clinic use. For cases and suspects, please attach a copy of radiology, pathology, and bacteriology reports not done at the State Laboratory Institute.

Evaluation:

ATS Classification: Check appropriate classification. If class 3 or 5 (case or suspect), complete site of disease.

HIV Risk Assessment: Required. Note: The Division has an HIV risk assessment tool that can be used as a guide for the assessment of patients who do not know their HIV status. Document if a risk was identified and any follow-up.

Medications: Complete when applicable. The 'Prescribed Medications: To Start on' date field is necessary for legal purposes to document the medication order. For cases and suspects, **the standard regimen is four-drug therapy for all patients.** Rifater should be used instead of INH, RIF, and PZA (for those who are not on directly observed therapy).

Patient Care Plan: Complete appropriate plan. **Note:** each patient should be assessed for the potential for adherence to treatment; **DOT is required for cases and suspects when risk factors for non-adherence are present** and is strongly recommended for certain high-risk preventives.

Reporting: It is the responsibility of the clinic to **report every clinically suspected or confirmed case of TB to the Division within 24 hours.** A toll-free number is available (1-888-MASSMTB), or the TB Case/Suspect Reporting Form can be used.

Comments: Optional for clinic use.

Signature: Signature(s) are required for legal purposes.

Distribution: The Initial Clinical Evaluation form and the TB History form should be **distributed together**, not separately. Original copy to Medical Records, a copy to the local health department of the patient's residence, and a copy the TB Division, Massachusetts Dept. of Public Health, State Laboratory Institute, 305 South St., Jamaica Plain, MA 02130.

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF TUBERCULOSIS PREVENTION AND CONTROL**

TB RECORD # _____

TB HISTORY FORM

NAME, LAST: _____ **FIRST:** _____

D.O.B.: ____ / ____ / ____ **Sex:** M ____ F ____

Street: _____

City: _____

Phone: (____) _____ ☐ None

Date: ____ / ____ / ____

☐ **TB Clinic:** _____

TUBERCULIN TESTS: (Date administered)

PPD Result ____ mm ____ / ____ / ____

Past PPD ____ mm ____ / ____ / ____

Past PPD ____ mm ____ / ____ / ____

B.C.G. ☐ No ☐ Yes: Age at Last Vaccination: _____

Referral Source: _____ **Phone:** (____) _____ **Civil Surgeon Referral:** ☐ Yes ☐ No

Primary Care Provider: _____ **Address:** _____

DEMOGRAPHIC DATA:

Race: ☐ White ☐ Black ☐ American Indian/Alaskan ☐ Asian /Pacific Islander **Healthcare:** ☐ Acute Care ☐ Long-term Care

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Drug Treatment Center ☐ Other: _____

Country of Birth: ☐ U.S. ☐ Other: _____ ☐ Shelter ☐ Correctional Services

Date of Entry to U.S.: (month/year) ____ / ____ ☐ Student ☐ Retired

Language spoken at home: _____ ☐ Interpreter needed ☐ Unemployed ☐ Other employment: _____

MEDICAL HISTORY: **Allergies:** _____ ☐ None Known

☐ Hx Hepatitis: A ____ B ____ C ____ ☐ Pregnant

☐ Hx TB Disease: Year: _____ Treatment: Months Rx: _____

☐ Hx Treatment of Latent TB Infection: Year: _____ Months Rx: _____

City/state where previous treatment received: _____

☐ Smoking ☐ Other: _____

Current non-TB Medications: _____

SYMPTOMS:

☐ Cough: ____ Productive ____ Non-Productive: # of Weeks ____

☐ Fever ☐ Hemoptysis ☐ Weight Loss

☐ Night Sweats ☐ Persistent Fatigue/Malaise

☐ Chest Pain ☐ Other S&S: _____

☐ **NO SYMPTOMS OF ACTIVE DISEASE NOTED**

RISK HISTORY:

HIV Status: ☐ Unknown ☐ Known ☐ Test Done, Results not shared

Check "Yes", "No" or "Unknown" for each of the following:

Yes No Unknown
☐ ☐ ☐

Close contact to a person with active TB ☐ Within the past 2 years ☐ More than 2 years ago

Source Case Name, LAST: _____, FIRST: _____

☐ ☐ ☐

Recent Converter (within past 2 years: \geq 10mm change

☐ ☐ ☐

Abnormal chest X-ray, consistent with old TB

☐ ☐ ☐

Newly arrived immigrant from any country with Class A/B TB (**Check Class**): ☐ Class A ☐ Class B1 ☐ Class B2

☐ ☐ ☐

Non-US born person from country with a high prevalence of TB:

(Africa, Asia except Japan, Central/South America, Eastern Europe, Caribbean, Middle East)

☐ ☐ ☐

Living, working, or extensive travel outside the USA within past 5 years to country with a high prevalence of TB

☐ ☐ ☐

Patient has one or more of the following underlying medical conditions: (**Check all that apply**)

☐ Insulin-dependent Diabetes Mellitus ☐ Steroid Therapy ☐ Malignancy (Cancer of head, neck, lung)

☐ Chronic Renal Disease/Hemodialysis ☐ Silicosis ☐ Hematologic Disorders (Leukemia, Lymphoma)

☐ Gastrectomy / Jejunioileal Bypass ☐ Organ Transplant ☐ Weight Loss \geq 10% of ideal body weight

☐ ☐ ☐

Resident of a high-risk setting within the past year: (**Check all that apply**)

☐ Prison/Jail ☐ Long Term Care ☐ Homeless Shelter

☐ ☐ ☐

Medically under-served: (**Check**) ☐ Homeless ☐ Migrant worker ☐ Other: _____

☐ ☐ ☐

Substance Abuse within the past year: (**Check all that apply**) ☐ IV Drug Use ☐ Excessive Alcohol Use

☐ Crack/Cocaine/Other

☐ ☐ ☐

Anergic (with a risk factor for TB)

COMMENTS: _____

Signature: _____, ☐ M.D.

Signature: ☐ R.N. _____

Instructions for completing the TB HISTORY FORM

General Instructions: The purpose of this form is to collect baseline information on the patient's demographics, medical history, and risk factors for TB. This form is only completed for the **initial visit**. The clinic or health department personnel may fill it out at the time of the clinic visit or prior to the visit. A referring health care provider could also complete it. **Please print legibly.**

These instructions address areas that may not be self-explanatory or have special instructions. Please fill form out as completely as possible. Optional fields are included primarily for clinic use as requested during piloting at clinic sites; most of the optional fields will not be entered into the Division's database. **Areas that are required are specifically noted in these instructions.**

TB Record #: Leave blank. The Division completes this upon data entry.

Identification demographics (left top box): Printing is faint, so addressographs can be used.
All bolded fields in this section are required.

Date and TB Clinic name: Required.

Referral Source Section: Source and Primary Care Provider fields are optional – for clinic use.

Civil Surgeon Referral – Immigrants who are adjusting their immigration status in the US are required to complete a medical screening. Civil Surgeons (physicians designated by Immigration and Naturalization Service) must plant and read a PPD on each applicant over the age of two. Any applicant with a reaction of 5MM or greater needs to be further evaluated at the TB clinic. Check this box.

Demographic Data: Required.

Employment Data: Check as many as apply with the exception of 'Unemployed' (no other box may be checked except student, if applicable). If a person is unemployed due to retirement, please check the 'Retired' box. 'Employed at' (place of employment) is an optional field – for clinic use.

Medical History:

History of Hepatitis: Check if pre-existing hepatitis (not due to TB drugs) and type A, B, or C.

'City/state where previous treatment received', 'Smoking', 'Other', and Current non-TB Medications' are optional fields – for clinic use.

Symptoms: Required.

Risk History: Required.

HIV Status: Check appropriate box for patient's knowledge of his/her HIV status. Patients who do not know their HIV status need to have a risk assessment done, with referral to Counseling and Testing services if an HIV risk is identified (document on Initial Clinic Evaluation Form).

Check 'Yes', 'No', or 'Unknown' for each risk factor. For risk factors with sub-boxes, check all that apply (at least one sub-box must be checked).

Steroid Therapy: Higher risk for progression to disease associated with prolonged high-dose steroid therapy:

≥ 15 mg/day of prednisone (or its equivalent) ≥ 1 month or ≥ 40 mg/day for ≥ 2 weeks.

Comments: Optional for clinic use.

Signature: Signature(s) is (are) required for legal purposes.

Distribution: The Initial Clinical Evaluation Form and the TB History form should be **distributed together**, not separately. Original copy to Medical Records, a copy to the local health department of the patient's residence, and a copy to the TB Division, Massachusetts Dept. of Public Health, State Laboratory Institute, 305 South St., Jamaica Plain, MA 02130.

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF TUBERCULOSIS PREVENTION AND CONTROL**

TB RECORD # _____

CASE/SUSPECT FOLLOW UP FORM

Hospital I.D. _____
NAME, LAST: _____ **FIRST:** _____
CITY: _____ **D.O.B.** ____/____/____ **Sex:** M ____ F ____
Complete for Change of Address or Phone only
Street _____ State _____
City _____ Zip Code _____
Phone (____) _____

☐ **Date of Visit:** ____/____/____
☐ **TB Clinic:** _____
Type of Visit: A - MD Visit B - Nurse Visit
____ A₁ x-ray ____ Clinic/BOH
____ A₂ w/o x-ray ____ Home Visit
☐ **Private Provider:** _____

IF NO LONGER ON CHEMOTHERAPY - COMPLETE THIS BOX ONLY

☐ Completed ____ mos therapy: ____/____/____
☐ Incomplete chemotherapy reason:
☐ Moved, records referred (**complete address change**)
☐ Lost, unable to locate
☐ Died: ____ TB ____ Not TB
☐ Other: _____
☐ Discharged from clinic ☐ Letter of discharge given to patient

DRUG MONITORING:

Assessment of Adverse Reactions: Check if present
☐ Unexplained Anorexia ☐ Rash
☐ Nausea/Vomiting ☐ Fever > 3 days
☐ Abdominal Tenderness ☐ Peripheral Neuropathy
☐ Persistent Fatigue ☐ Vision Changes
☐ Malaise ☐ Hearing Changes
☐ Dark Urine ☐ Headache
☐ Jaundice/Icterus ☐ Hair Loss
☐ Other S&S: _____
☐ **NO ADVERSE REACTIONS NOTED**

Baseline ALT: _____
ALT Result: ☐ WNL ☐ ABNL _____ ☐ Not Done /Ordered
Comments: _____

ADHERENCE ASSESSMENT:

☐ Treatment Adherence Assessed ☐ Urine Checked for INH/RIF
Interrupted Therapy: ☐ Yes: # of Doses _____ ☐ No
PLAN:
Continue: ☐ Self-Administered Therapy ☐ Directly Observed Therapy
Start Directly Observed Therapy: ☐ Daily ☐ Intermittent: ____ X/Week
Person(s) performing DOT: _____
☐ Hold Meds temporarily due to: ☐ Abnormal ALT ☐ Side Effects
☐ Patient Education Reinforced: _____

Sputum ordered: ☐ Yes ☐ No Chest X-ray ordered: ☐ Yes ☐ No
Other Tests Ordered: _____

CLINICAL STATUS: ☐ Improving ☐ Worsening ☐ No Change

Weight: _____
Comments: _____

Follow-up Chest X-Ray: Date: ____/____/____ ☐ Not Done

Results: ☐ Normal ☐ Abn/Cavity ☐ Abn/Non-Cavity
Status: ☐ Stable ☐ Improving ☐ Worsening

Brief description of findings: _____

Bacteriology: ☐ No Bacteriology Pending

Source: _____ Date Collected: ____/____/____

Smear Result: ☐ Neg ☐ Pos ☐ Pending

Culture Result: ☐ Neg ☐ Pos ☐ Pending

Sputum Conversion Documented: ☐ No ☐ Yes Date: ____/____/____

No Positive Bacteriology - Evidence of Active TB:

☐ Clinical Response ☐ X-Ray Change
☐ Epidemiologic Link ☐ Pathology Only

Details: _____

Classification Status: ☐ Case - Class 3 ☐ Suspect - Class 5

Disease Site(s): ☐ Pulmonary ☐ ExtraPul: _____

☐ **Active TB ruled out:** ____ Not TB ____ Old TB ____ Class 2

MEDICATION STATUS: **mos. completed,** **mos. remaining**

DRUG RESTART	DOSAGE	FREQ	START	STOP	
Rifater					
Rifamate					
INH					
RIF					
PZA					
EMB					

Next Visit: _____ **Country of Birth:** _____

☐ Interpreter needed next visit: Language: _____

Comments: _____

Signature: _____ ☐ R.N. ☐ M.D. **Toll-Free Reporting Number: 1-888-MASSMTB (627-7682)**

**MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
DIVISION OF TUBERCULOSIS PREVENTION AND CONTROL**

TB RECORD # _____ PREVENTIVE THERAPY FOLLOW UP FORM

Hospital I.D. _____
NAME, LAST: _____ **FIRST:** _____

CITY: _____ **D.O.B.** ____/____/____ **Sex:** M ____ F ____
COUNTRY OF BIRTH: _____ ☐ Contact
Complete for Change of Address or Phone only
 Street _____ State _____
 City _____ Zip Code _____
 Phone (____) _____

Date of Visit: ____/____/____
TB Clinic: _____
Type of Visit: A - MD Visit B - Nurse Visit
 _____ A₁ x-ray _____ Clinic/BOH
 _____ A₂ w/o x-ray _____ Home Visit
 No Visit: ____ Record review only
Preventive Therapy Status
☐ No longer on therapy **Complete Part A only**
☐ Still on therapy ☐ **Complete Part B**
☐ Last clinic visit - to complete therapy on: ____/____/____
☐ Letter of Discharge given to patient

PART A: COMPLETE IF NO LONGER ON THERAPY
☐ Completed ____ mos: ____/____/____
☐ Incomplete preventive therapy reason:
☐ Diagnosed with active TB disease
☐ Moved, records referred (**complete address change**)
☐ Lost, unable to locate
☐ Died
☐ Discontinued by physician for adverse reactions
☐ Patient stopped on own initiative
☐ Discontinued on medical advice for other than adverse reactions
☐ Pregnancy ☐ Other: _____

PART B: MEDICATION STATUS:
 _____ mos. completed, _____ mos. Remaining

DRUG	DOSAGE	FREQ	START DATE	STOP DATE	RESTART DATE	FINAL STOP DATE
INH						
RIF						

Child's Weight: _____
Comments: _____

PART C: EVALUATION

DRUG MONITORING:
Assessment of Adverse Reactions: Check if present
☐ Unexplained Anorexia ☐ Rash
☐ Nausea/Vomiting ☐ Fever > 3 days
☐ Abdominal Tenderness ☐ Peripheral Neuropathy
☐ Persistent Fatigue ☐ Jaundice/Icterus
☐ Malaise ☐ Dark Urine
☐ Headache ☐ Hair Loss
☐ Other S&S: _____
☐ **NO ADVERSE REACTIONS NOTED**
 Baseline ALT: _____
 ALT Ordered: ☐ Yes ☐ No
 ALT Result: ☐ WNL ☐ ABNL _____ ☐ Not Done
 Other Test Results: _____
Comments: _____

ADHERENCE ASSESSMENT:
☐ Treatment Adherence Assessed ☐ Urine Checked for INH/RIF
PLAN:
 Continue: ☐ Self Administered Therapy ☐ Directly Observed Therapy
 Start Directly Observed Therapy: ☐ Daily ☐ Intermittent: ____X/Week
☐ Hold Meds temporarily due to: ☐ Abnormal ALT ☐ Side Effects
☐ R/O Pregnancy
☐ Patient Education Reinforced about: _____
☐ Tests Ordered: _____
Comments: _____

Next Visit: ____/____/____
☐ Interpreter needed next visit: Language: _____

Signature: _____ ☐ R.N. ☐ M.D.

Massachusetts Department of Public Health
Division of Tuberculosis Prevention and Control
305 South Street Jamaica Plain, MA 02130

Reporting: (617) 983-6989
1-888-MASS-MTB (Toll Free)
FAX: (617) 983-6990
All Reporting Confidential

TB Case / Suspect Reporting Form

Please Circle, where appropriate:

Patient Name: _____, _____ Sex: M F Birth Date: _____
(last) (first)
Street Address: _____ City/Town: _____ State: _____ Zip: _____
Tel: (Home) (____) _____ Place Of Birth: _____ Primary Language: _____
Work Place: _____ Tel: (____) _____ Next of Kin: _____ Tel: (____) _____

Mantoux (PPD) Test: Done Not Done Unknown	Date Performed: _____	Results: _____	MM
Chest X-Ray: Done Not Done Unknown	Date Performed: _____		
Results of Chest X-Ray: Normal Abnormal, Non-Cavitary Abnormal, Cavitary			
Site(s) of Disease: _____	Type of Specimen Collected: _____		
Date Collected: _____	Smear Results: Positive Negative Unknown Not Done		
	Culture Results: Positive Negative Unknown Not Done		

Medications Begun: Yes No Unknown	Date Medications Started: _____
Isoniazid (INH): _____ Mg	Rifater (RFT) (fixed combination of INH, RIF, PZA): _____ Tabs
Rifampin (RIF): _____ Mg	Other: _____
Pyrazinamide (PZA): _____ Mg	Other: _____
Ethambutol (EMB): _____ Mg	Other: _____

Is Patient Hospitalized? Yes No	Hospital: _____	City/Town: _____
Adm. Date: _____	Estimated Disch. Date: _____	Hospital Record #: _____
Discharge Planning Contact Person: _____		Tel: (____) _____

Person Completing Form: _____ Tel: (____) _____ Date: _____

Agency/Facility Name: _____

Primary Health Care Provider: _____ Tel: (____) _____

TB Care Provider: _____ Tel: (____) _____

Comments: _____

TB Reporting Instructions, Information and Services
(617) 983-6970 - main number - Division of Tuberculosis Prevention and Control

Reporting - 24 hour lines: (617) 983-6989, 1-888-MASS MTB (toll free), FAX: (617) 983-6990
(Regulation 105 CMR 365.500 or 105 CMR 300.140 -D)

1. **Notify** the Division within 24 hours of all confirmed and clinically suspected cases of TB
2. **Fax / phone** notification necessary for: Hospital patients and others requiring discharge planning

Standard Tuberculosis Treatment for Active Disease

For all TB Cases and Suspects: begin with four drugs until drug sensitivities available
(Isoniazid, Rifampin, Pyrazinamide, Ethambutol or Streptomycin)

Fixed Combination Drugs: recommended when patient on daily doses
Rifater (INH, RIF, PZA) initially; Rifamate (INH, RIF) for continuation phase

Failing Regimen: To prevent resistance, always add at least two TB drugs at the same time

Consultation and list of Free TB Clinics available at the Division of TB Prevention and Control

Case Management Services

Nurse Case Manager **required** for all cases and suspects: Assigned by the local health department

Coordinates medical, nursing, outreach, and social service systems needed to begin and complete appropriate therapy

Responsible for case and contact investigations, nursing care plans, and patient education

Arranges for Directly Observed Therapy (DOT) when indicated

State regional nurses collaborate with local nurses regarding case management services

Discharge Planning

(Regulation 105 CMR 365.600 requires TB discharge planning in collaboration with state and local health departments)

Starts When: TB diagnosed or suspected (clinical/laboratory evidence or patient on TB drugs)

Pre-Discharge Conference Required: Include local health department nursing case manager, providers and discharge planners

Home assessment by local health department nursing case manager **necessary to:**

1. Prevent putting potentially vulnerable household members at risk - especially children
2. Coordinate community follow-up for continuation and completion of therapy

Infectious Patients - Special Considerations: Call the Division of TB Prevention and Control

Name: Last: _____, First: _____

DRUG O'GRAM

Year: _____

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15

DRUG	Month
Smear (- / +)	_____
Culture (- / +)	_____
Sensitivities (✓ = done)	_____

RIFATER	X--X = drug
RIFAMATE	S = sensitive
ISONIAZID	R = resistant
RIFAMPIN	
PYRAZINAMIDE	
ETHAMBUTOL	
STREPTOMYCIN	
KANAMYCIN	
CYCLOSERINE	
ETHIONAMIDE	
PAS	
OFLOXACIN	
CIPROFLOXACIN	
CAPREOMYCIN	
RIFABUTIN	
AMIKACIN	
OTHER _____	
OTHER _____	



DIVISION OF TB PREVENTION & CONTROL

OF _____

MONTH _____

DIRECTLY OBSERVED THERAPY (DOT) LOG

Patients Name: _____ Start Date: ____/____/____ Designated Days/Times: _____

MEDS-DOSE-FREQ	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
ISONIAZID																															
RIFAMPIN																															
ETHAMBUTOL																															
PYRAZINAMIDE																															
PYRIDOXINE																															
LEVOFLOXACIN																															
OFLOXACIN																															
STREPTOMYCIN																															
KANAMYCIN																															
PAS																															
ETHIONAMIDE																															
OTHER																															
COMMENTS:																															

Codes: (O) Out of medication (R) Refused (S) Sick/Unable to take medicine (N) Not Home (W) Weather

HCW Signature: _____ Initials: _____ Patient Signature: _____ Initials: _____

Patient Contract for Self-Administered Therapy

Tuberculosis (TB) is a curable and preventable disease. I know that I have TB and need to be treated. I agree to the following conditions:

1. I will take my pills as prescribed by my doctor, for as long as needed.
2. I will keep all my appointments with the clinic, doctor, nurse and/or outreach worker.
3. I will have all required medical tests, such as x-rays, sputum, urine and blood tests.

I understand that if I fail to keep my appointments and take my pills that I may spread the disease to others, including my family and friend. If this happens, I will need directly observed therapy (DOT) where someone watches me take my pills or I may need to be hospitalized.

Case Manager Signature: _____

Patient Signature: _____

Patient Contract for Directly Observed Therapy

Tuberculosis (TB) is a curable and preventable disease. I know that I have TB and need to be treated. I understand that the health department nurse will watch me take my pills (directly observed therapy - DOT) and I agree to the following conditions:

4. I will keep all my DOT appointments with the nurse and/or outreach worker and take my pills as prescribed by my doctor, for as long as needed.
5. I will keep my appointments with the clinic and doctor.
6. I will have all required medical procedures, such as x-rays, sputum and blood tests.

I understand that if I fail to keep my appointments and take my pills that I may spread the disease to others, including my family and friends, and that I may have to be hospitalized.

Case Manager Signature: _____

Patient Signature: _____

HIV RISK ASSESSMENT TOOL

Patient Initials: _____ Date of Birth: ____/____/____

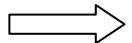
Assessment Date: ____/____/____

Use of this High Risk Assessment Tool:

- ▶ This form is designed to assess the TB patient's HIV risk.
- ▶ It is preferable for the questions to be asked by a nurse or physician.
- ▶ Patients should fill out the form only if there are no language or literacy barriers.
- ▶ The questions on the reverse side should be read aloud to the patient and the patient response should be marked in the appropriate box.
- ▶ The form should then be placed in the patient chart.
- ▶ Anyone who answers yes to questions 1-7 and 10 should be referred for HIV counseling and testing.

FOR OFFICE USE ONLY:

____ HIV risk assessment performed
____ HIV risk assessment previously performed
____ HIV risk assessment documented in chart
____ HIV risk assessment form in chart
____ HIV counseling and testing referral made: ____/____/____
 ____ performed on site
 ____ performed at another site where _____



To be read aloud to patient before beginning HIV risk assessment:

“So that you get the best care possible in the TB clinic, we need to ask some questions about your TB history and about activities that can put you at risk for HIV. Having TB infection **does not** mean you are at greater risk for HIV. But if you already have both TB infection and HIV, you are more likely to get active TB disease. So, part of our job is to make sure every patient seen in this TB clinic knows what the risks for HIV are and is asked about those risks. We know that asking these questions may make you feel uncomfortable but please remember that every patient is asked the same HIV questions, no matter what age, race, gender, or what country they are from. I will now read the questions. Please answer yes or no as it applies to you. Your answers are kept confidential.”

HIV Risk Assessment Questionnaire

- 1) Do you think you are at risk for HIV? Yes_____ No_____
- 2) Sometimes doctors and nurses in different parts of the world cannot get clean needles and equipment for their patients. This can put people at risk for HIV. Do you think this is a risk for you? Yes_____ No_____
- 3) People are at risk for HIV if they use/used to use unclean needles, share/used to shared unclean needles or their partner uses/used to use unclean needles. Do you think this is a risk for you? Yes_____ No_____
- 4) People or their partners who do not regularly use a condom during sex with someone at risk for HIV are themselves at increased risk for HIV. Do you think this is a risk for you?
Yes_____ No_____
- 5) Having sex with people who inject drugs or having sex with men who have sex with men increases the risk for HIV. Do you think this is a risk for you? Yes_____ No_____
- 6) Having sex with many people or having sex with someone who has had many sex partners increases the risk for HIV. Do you think this is a risk for you? Yes_____ No_____
- 7) People who had a blood transfusion or received blood products since 1978 are at increased risk for HIV. Have you had a blood transfusion or received blood products since 1978?
Yes_____ No_____ If yes, what year? _____ Where_____
- 8) Would you like to know more about condom use education? Yes_____ No_____
- 9) Would you like more information on HIV? Yes_____ No_____
- 10) Would you like a referral for HIV counseling and testing? Yes_____ No_____

DRUGS TO TREAT TB: DOSES AND SPECIAL CONSIDERATIONS

FIRST LINE TB DRUGS				
Drug	Daily Adult Dose	Twice Weekly Adult Dose	Route	Adverse Reactions
Isoniazid (INH)	5 mg/kg Max. 300 mg	15 mg/kg Max. 900 mg	P.O./ I.M.	hepatotoxicity/hepatitis, peripheral, flu-like syndrome, neuropathy, hypersensitivity,
Rifampin (RIF)	10 mg/kg Max. 600 mg	10 mg/kg Max. 600 mg	P.O./I.V.	Orange discoloration of urine and other secretions, nausea, vomiting, hepatitis, fever, purpura (rare), reduces levels of many drugs: Protease Inhibitors, birth control pills, Methadone, Warfarin, and Theophylline Metformin
Rifamate (RFM) (Isoniazid and Rifampin) A fixed-dose combination of 150 mg Isoniazid and 300 mg Rifampin in each capsule	two capsules	N/A	P.O.	Same as for Isoniazid and Rifampin
Pyrazinamide (PZA)	15-30 mg/kg Max. 2 Grams	50-70 mg/kg Max. 4 Grams	P.O.	hepatotoxicity, hyperuricemia, arthralgias, skin rash, gastrointestinal irritation
Rifater (RFT) (Isoniazid, Rifampin, and Pyrazinamide) A fixed-dose combination of 50 mg Isoniazid, 120 mg Rifampin, and 300 mg Pyrazinamide in each tablet	under 99 lb. - four tablets 99 - 120 lb. - five tablets over 120 lb. - six tablets		P.O.	Same as for Isoniazid, Rifampin, and Pyrazinamide
Ethambutol (EMB)	15-25 mg/kg	50 mg/kg	P.O.	optic neuritis, decreased visual acuity and red-green color discrimination, skin rash
Streptomycin (SM)	15 mg/kg Max. 1 Gram (10 mg/kg up to 750 mg for persons age 60 and over)	25-30 mg/kg Max. 1.5 Grams	I.M.	ototoxicity, nephrotoxicity, hypokalemia

SECOND LINE TB DRUGS

Drug	Daily Adult Dose	Route	Adverse Reactions
Kanamycin, Amikacin, Capreomycin	15-30 mg/kg	I.M./I.V.	renal and auditory toxicity, vestibular toxicity (rare), hypokalemia
Ethionamide	15-20 mg/kg 500 –1000 mg daily in divided doses	P.O.	gastrointestinal disturbance, arthralgias, hepatotoxicity, hyperthyroidism, metallic taste and distorted smell, severe acne
Cycloserine	15-20 mg/kg 250-1000 mg daily divided doses	P.O.	psychosis, personality changes, rash, Impaired coordination, convulsions (rare), depression, increases Dilantin levels
Para-amino salicylate (PAS)	150 mg/kg 8-12 Grams daily in, anemia divided doses	P.O. Tablets, powder, or granules	gastrointestinal disturbance, sodium load, increases Dilantin levels, hemolytic in patients with G6PD deficiency
Ofloxacin	400-800 mg daily in divided doses	P.O./I.V. bolus	abdominal cramps, nausea, diarrhea
Ciprofloxacin	750-1500 mg	P.O./I.V. bolus	abdominal cramps, nausea, diarrhea, rash, Headache, photosensitivity, insomnia
Rifabutin- used as an alternative to Rifampin for HIV positive persons on Protease Inhibitor therapy (use with Indinavir only)	150 mg daily	P.O.	fever, headache, flu-like syndrome gastrointestinal symptoms, decreases AZT serum levels

Source Case Investigation Policy and Procedure Latent Tuberculosis Infection (LTBI) in Children less than 1 year of age

Massachusetts Policy:

The Massachusetts Department of Public Health, Division of Tuberculosis Prevention & Control's policy is to perform source case investigations for any child less than 1 year of age diagnosed with latent tuberculosis infection.

Rationale:

The Massachusetts Advisory Committee for the Elimination of Tuberculosis (MACET) views source case investigation as fundamental to preventing tuberculosis in children. When a child has latent TB infection, we know that TB was transmitted relatively recently. The person with infectious TB who is responsible for transmitting the *M. tuberculosis* organism to the child is called the source case. Source case investigation is a method used to find the source of TB transmission when recent transmission is likely. The younger the child, the greater the chance of locating the source case, since the infection is more likely to have been recent and an infant's circle of contacts is usually much smaller than an older child's. Once the source case is found, he or she should be treated to prevent further spread of tuberculosis to others.

Procedure:

Conduct a source case investigation for children, less than 1 year of age who have a positive tuberculin skin test and who have not been identified as a close contact to a known suspect/case of infectious tuberculosis.

1. Identify members of the child's household and others who have had close continuous contact with the child (e.g. babysitters, day care staff, friends or family), or with whom the child spends a significant amount of time.
2. Evaluate anyone with signs and symptoms of TB or with a history of TB.
3. Refer child's contacts for a medical evaluation if symptomatic or with a positive reaction to the tuberculin skin test. The evaluation is preferably done at a TB clinic.

NOTE: All children with LTBI, regardless of age, should be evaluated for treatment.

